



Health Industry Business
Communications Council

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LETTER OF TRANSMITTAL

January 24, 2019

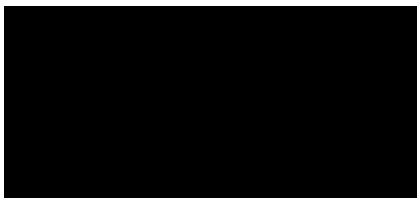
To The European Commission,

HIBCC is pleased to submit to the European Commission our enclosed application to be designated as a UDI Issuing Entity. The application includes supporting attachments and material that is numbered to correspond with the information requested in your Call for Applications.

We look forward to working with the Commission as it launches this important initiative.

Please contact me if additional information or clarification is needed.

Sincerely,



President & CEO



HIBCC European Commission Issuing Entity Application

1. Name, address, and phone number of the applicant;

Name: Health Industry Business Communications Council Global Office
Address: 2525 E. Arizona Biltmore Circle, Suite 127, Phoenix, AZ 85016
Phone Number: +1 (602) 381-1091

2. Detailed information regarding the applicant's organisation, including the description of any financial or other relationship between the applicant and any manufacturer or governmental institutions or organisation;

HIBCC was established in 1984 by a consortium of healthcare supply chain trade associations for the purpose of creating a bar code (auto-ID) labeling standard for medical devices. The HIBC Supplier Labeling Standard (SLS) (Attachment 1) was successfully implemented and was followed by a series of related standards for auto-ID labeling, electronic data interchange, provider identification, and other supply chain processes. Over time these have evolved with changing technologies and user requirements. The HIBCC office was created to serve as the global secretariat and accredited standards development organization (SDO) for the SLS and our other standards. We were thereafter accredited by the American National Standards Institute (ANSI) (Attachment 4), recognized as part of the International Organization for Standardization (ISO) network (Attachment 2), the Committee for European Normalization (CEN), etc. We are also a designated Issuing Agency for the US Food and Drug Administration (FDA) UDI regulation.

HIBCC is registered and structured as a 501(c)6 non-profit corporation under US law by the US Internal Revenue Service (Federal EIN 36-3313052). In addition to registering companies and organizations with company identifiers (known as Labeler Identification Codes) for UDI and product labeling, HIBCC also provides fee-based database services to companies and government agencies that utilize our Health Industry Number (HIN) System of healthcare provider identifiers. In some cases, HIN users and licensees may also be HIBC SLS product labelers; however HIN services do not relate to the UDI system or our LIC application process.

HIBCC standards are maintained in conformance with standard operation procedures, and are designed to assure conformity, patient safety, and supply chain efficiency. Various companies, healthcare institutions, and other organizations, including government agencies, participate in our technical committees. All participants are required to comply with HIBCC's Antitrust Policy (Attachment 7) and HIBCC's Conflict of Interest Policy (Attachment 8).

HIBCC supports a network of affiliated organizations, such as the European Health Industry Business Council (EHIBCC) and others, to provide technical support to our labelers. However, changes and/or maintenance to the standard, as well as policy, oversight and registration maintenance are the responsibility of HIBCC.



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3. Detailed description of its system for the assignment of UDIs, including description of any standard or criteria applied;

The HIBC Supplier Labeling Standard (SLS) (Attachment 1) is accredited by ANSI, and in conformance with the EU MDR and FDA UDI rule. Labelers using the HIBC SLS are required to strictly adhere to the standard in order to be in conformance with all UDI regulations from which they will derive their device and production identifiers. In order to become a labeler, the interested party will register with HIBCC to obtain a Labeler Identification Code (LIC). HIBCC will then assign a unique 4-digit, alphanumeric code (such as B123) to identify the registrant. The LIC code is never duplicated or reassigned and thus is distinctly unique to that registrant/labeler. HIBCC maintains the LIC assignments in an internal database.

The HIBC Supplier Labeling Standard (SLS) is the guideline from which a labeler will derive their UDI data. The HIBC SLS specifies the type of information that should be encoded and the method of doing so.

For instance, the primary data string requires a "+" flag character, the 4-character LIC, a 1-18 character product or catalog identifier, a one-digit unit of measure and a single-digit check characters. Elements of this data string become the device identifier.

Secondary information such as lot/batch number, serial number, expiry date and/or date of manufacture are prescribed as well, and will provide the method for developing the production identifier. (Please reference the attached HIBC SLS for specific encoding requirements.)

Because the LIC assignment is unique to the individual labeler and never reassigned to a different labeler, when attached to their own product code it inherently creates a unique data string. No two UDIs could be alike because of the uniqueness of the LIC assignment. And because the HIBC SLS is variable length, and alphanumeric there are virtually limitless numbers of possible UDIs.

Attached are the American National Standard Institute (ANSI) approved HIBCC Standard Operating Procedures, which document the required process for updating a standard (Attachment 9). All updates to the HIBC Supplier Labeling Standard are made in an effort to support the EU MDR requirements and provide additional clarification surrounding any common areas of confusion. All versions of the standard are backward compatible to ensure that any UDI created in a previous version maintains compliance.

All new versions of the HIBC Supplier Labeling Standard (SLS) are approved by ANSI and subsequently published in their publication "Standards Action". HIBCC posts all new versions of the standard on our website and sends an email notification describing any updates to all HIBCC labelers. Additionally, HIBCC works with labelers one-on-one to review all changes as requested.



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4. Copies of the application forms, guidelines, instructions, and other materials the applicant will send to manufacturers who plan to use the applicant's system for the assignment of UDIs. Where those materials are still under preparation, the applicant shall provide a detailed plan for adoption of those materials;

All labelers receive a welcome letter (Attachment 15) upon registering with HIBCC, which confirms the 4-character LIC assignment. Labelers are also given the latest copy of the Supplier Labeling Standard (Attachment 1) and the relevant technical guidance documents (Attachment 11, 12, 5, and 6). All guidance documents are created and/or updated constantly. HIBCC plans to release EU MDR specific guidance documents once the MDR guidelines are finalized.

5. Detailed description of the applicant's policies and procedures for determining whether manufacturers may use the applicant's system;

The HIBC Supplier Labeling Standard is an open standard and available to all parties that elect to use it.

The HIBCC organization is the sole assigner of the Labeler Identification Code (LIC). An application form (Attachment 14) and payment of a one-time fee (Attachment 10) is required for assignment of an LIC. HIBCC released a Clarification on LIC Fees (Attachment 18) in 2016 to ensure the process maintained clear and transparent for all parties.

6. Description of the applicant's policies/procedures for dealing with manufacturers' deficiencies in using correctly the system for the assignment of UDIs, including for monitoring corrections;

HIBCC will notify labelers of deficiencies in the use of the HIBC Supplier Labeling Standard by letter (Attachment 3). This notice requires the organization to take corrective action within 30 days of receiving the letter. The most common action would be to update an existing LIC or apply for a new LIC.

In the case of an organization using an LIC that is not registered to them, HIBCC would issue a cease and desist letter. Additionally, HIBCC will notify all regulatory bodies including the European Commission and the U.S. FDA, in the event that an organization is using an unregistered HIBCC prefix.

7. Description of business model and fee system, with an explanation and rationale of any fee waiver or reduction available;

HIBCC has been registering labelers for 30 years, and will further enhance processes to meet EU MDR requirements. The registration process requires a new labeler to pay a one-time application to HIBCC for assignment of the Labeler Identification Code (LIC). Thereafter, there are no reoccurring fees to the labeler to maintain their LIC. HIBCC continues to provide technical support and guidance to labelers at their request. The assigned LIC is applied globally, and can be used for the labeling of a registrant's entire product line.



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There are no fees for individual product code assignments. Additionally, because of the variable-length, alphanumeric structure of the HIBC Supplier Labeling Standard, there are virtually limitless possible combinations to create a UDI compliant data string.

The LIC registration fee is based upon a progressive fee-schedule that is tied the labelers gross annual sales in its immediate prior fiscal year. LIC registration fees are extremely modest and because of their progressive schedule to do not impose a burden on small companies. We estimate that the vast majority of the medium to large companies already have a HIBC LIC or GTIN, therefore we believe the majority of new applicants will be at low-end of the fee schedule. (See Attachment 14 and 10 for application and fee schedule.)

8. Detailed description of the applicant's electronic data management system;

HIBCC currently maintains numerous databases for the health care industry and routinely distributes the data via various mediums including hard format, Electronic Data Interchange (EDI) and web-based services. These data distribution processes occur daily, weekly and quarterly. As such HIBCC is well positioned in terms of experience and infrastructure to provide electronic data in a format compatible with European Union data systems.

The draft guidance on the Eudamed database is currently being reviewed by HIBCC so that it can plan for the development of compatible systems when the final specification is released.

9. Description of the tools or services made available by the applicant allowing to check data quality in the EU database (Eudamed);

The "HIBCC UDI and Bar Code Generator" (Attachment 19) is a free utility available on the HIBCC website that allows labelers to generate sample UDIs and barcodes to the specifications in the HIBC standard. The utility currently creates the UDI Device Identifier in the correct format for GUDID submissions to assist labelers in achieving UDI compliance. The utility is updated in conjunction with the HIBC standard. HIBCC will make updates and enhancements to this utility to conform with the Eudamed database requirements.

HIBCC has recently launched a modification to its existing online UDI Generator Utility, which will compare LICs entered by labelers to our database in order to confirm that the LIC is valid (Attachment 19). This process will provide the labeler with a mechanism to confirm that they are using their assigned LIC.

HIBCC plans to offer a certification service beginning in 2019 which will examine sample labels and UDIs for compliance to the HIBCC Standard. The certification service will be voluntary and offered to all HIBCC labelers.



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The "HIBCC UDI Decoder" (Attachment 20) is a free mobile application for iOS and Android platforms that scans and parses the information in a HIBC auto-ID symbol. This application is not intended to replace any barcode verification process. It is meant as a tool to help anyone become more familiar with the HIBC standard.

10. The form “Applicant’s undertakings”, signed by the applicant organisation’s legal representative in the European Union;

Per our call with EC staff on January 17, 2019, HIBCC will be opening an additional administrative in Brussels to support the EU MDR. HIBCC will continue to utilize affiliate organizations in Europe, i.e. EHIBCC, for technical support. HIBCC will keep the EC updated on the progress of the administrative office and of any changes in the legal representative. Please see Attachment 21 for the signed “Applicant’s Undertakings” document.

11. Detailed information and, if available, market studies on the readability of UDI carriers which are compliant with the applicant's technical specification by the readers generally available to economic operators and healthcare institutions within the EU.

When the Health Industry Supplier Labeling Standard (HIBC SLS) was developed in 1984, the specification specifically stated that Auto-ID symbols and specifications for the standard were to be in conformance with universally approved and accepted symbologies, as well as printing, encoding, and scanning specifications. As the standard evolved to include small-package and two-dimensional symbols the standard has continued to adhere to those requirements. These specifications are as required by internationally recognized governance bodies such as ISO, AIM International, etc. Thus, HIBCC has never encountered an instance in which our standards specification did not conformed to these norms.

ANSI/HIBC 2.6
THE HEALTH INDUSTRY
SUPPLIER LABELING STANDARD
FOR PATIENT SAFETY &
UNIQUE DEVICE IDENTIFICATION (UDI)



An American National Standard (ANS)



AMERICAN NATIONAL STANDARD

Approval of an American National Standard requires verification by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer.

Consensus is established when, in the judgment of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made toward their resolution.

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**THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD:
FOR PATIENT SAFETY &
UNIQUE DEVICE IDENTIFICATION
(HIBC / SLS / UDI)**

**SECRETARIAT:
HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL (HIBCC)**

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HIBCC Standards are supported globally. HIBCC Standards are developed in accordance with the procedures of the American National Standards Institute (ANSI) and in consultation with our affiliates and other interested parties. For additional information and support options, contact HIBCC via email at info@hibcc.org or by calling 602.381.1091 (use country code '001' if calling from outside of the United States).

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Foreword

Automatic identification technology is continually evolving. As technological advances prove applicable to the health care industry, they will be incorporated into revisions of this standard, wherever possible. However, every attempt will be made to maintain the existing data structures, thereby allowing new technology to be introduced into systems in a non-disruptive manner. HIBCC recognizes that this standard is a technology driven solution to improvement of health care delivery. As new technology becomes widely available, the standard will be modified to incorporate the advantages of the new technologies.

1.0 Scope

This document describes the voluntary HIBC Supplier Labeling Standard for products distributed within the health care industry. Labelers (manufacturers) of health care products are strongly encouraged to identify their products with consistently readable symbols in accordance with the standards described herein.

1.1 Symbol Quality Compliance and Printing Assistance

Printed bar code symbols must meet or exceed the quality requirements of Section 5 and be easily scannable by standard bar code scanners at the point of use. Labelers having questions about or problems meeting the requirements of this standard should contact HIBCC in Phoenix at (602) 381-1091.

2.0 Supplier Labeling Data Structures

It is intended that all health care products be labeled with a Primary Symbol, which identifies the labeler in an internationally consistent and unique manner, the product code, and the unit of measure. Secondary information is useful to distributors and providers and, at the discretion of the labeler, should be added.

2.1 Primary Data Structure (Device Identifier)

The primary data structure contains an indication of the labeler of the item, the item, the packaging level, and a Check Character. Once constructed from these four elements, these structures should not be parsed. The labeler identification is a data element that is controlled by the Health Industry Business Communications Council (HIBCC). A labeler that chooses to utilize the HIBC Labeler Identification Code (LIC) should follow the HIBC LIC data and symbology format.

2.1.1 HIBC LIC Primary Data Structure (Device Identifier)

The HIBC LIC Primary Data Structure format encodes a “+” data identifier of the HIBC Supplier Data Structure, a 4 character Labeler Identification Code (LIC), a 1 to 18 character Product or Catalog Number (PCN), a one-digit Unit of Measure Identifier (U/M), and a single Check Character (C).

The format for the Primary Data Structure format follows (for illustration purposes, the product identifier, or PCN, is shown at its maximum length, 18 characters, therefore the maximum symbol length is 25 characters): See Table 1

+IIII P P P P P P P P P P P P P P P P P P U C

where: (see below)

Table 1

Field Descriptor	Field Length	(F)ixed Length (V)ariable Length	Field Description
+	1	F	HIBC Supplier Labeling Flag Character “+”
I	4	F	Labeler Identification Code (LIC) an alphanumeric number, with the first character always being alphabetic.
P	1-18	V	Labelers Product or Catalog Number (PCN). Alphanumeric data
U	1	F	Unit of Measure ID, Numeric value only, 0 through 9, where 0 always represents a single unit. 1 to 8 are used to indicate different packaging levels above the unit of use. The value 9 is used for variable quantity containers when manual key entry or scan of a secondary will be used to collect specific quantity data. The labeler should ensure consistency in this field within their packaging process.
C	1	F	Check Character calculated from the above characters. (see Appendix B2)

The Labeler Identification Code (LIC) is assigned and maintained by HIBCC. The first character of this field will always be an alphabetic character. The LIC may identify a labeler to the point of separate subsidiaries and divisions within a parent organization.

The Product or Catalog Number (PCN) shall be compressed to eliminate embedded spaces and special characters. Special characters shall not be used in this field. The allowed characters are A through Z and 0 through 9. Examples of this compression follow:

655-9	would become	6559
24-86-2S	would become	24862S
84/XPG	would become	84XPG
MP 15 86-G.....	would become	MP1586G
92.885*BK	would become	92885BK

This compression impacts only the machine-readable representations of the PCN and its associated human readable interpretations. Other external package markings and catalog listings covered by this standard remain the prerogative of the individual labeler.

The Unit of Measure Identifier (U/M) is a numeric representation of the relative level of packaging (0 to 9) with 0 being the lowest level or “unit-of-use”. For example, a labeler might pack unit-of-use items in a box, boxes in a carton, and cartons in a case. One way of labeling this example would be, unit-of-use = 0; Box = 1; Carton = 3; and Case = 5. It may be that a unit-of-use is packaged, however, in a box. For instance, individual cotton swabs would be considered the unit-of-use and may go unmarked. Consequently, the box in which the cotton swabs were packaged would be marked with the HIBC Supplier Primary Data Structure with a 1 or greater in the U/M field. Note that U/M identifiers are arbitrarily assigned by each labeler and must be internally consistent.

2.1.2 Primary Data Structure in Electronic Data Interchange

For information about communicating Primary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database.

2.1.3 Reuse of HIBC Primary Identifier

A HIBC Primary Identifier shall not be reissued to any other item, even if the item to which it has been assigned has been discontinued, or superseded by another product.

2.1.4 Definition of the HIBCC Universal Product Number (UPN)

The HIBCC UPN is the Primary Identifier excluding the “+” character and the Check Character.

2.2 Secondary Data Structure (Production Identifier)

Optional secondary data elements are used in conjunction with primary data elements, for example to encode expiry date and/or Lot/Batch/Serial Number. Appendices E and F describe the secondary data fields in detail.

2.2.1 HIBC LIC Secondary Data Structure

The format for the HIBC Secondary Data Structure is shown in Table 2.

Table 2

Field Descriptor	Field Length	Field Description
+	1	Internationally recognized, unique, HIBC Supplier Labeling Data Identifier Flag Character, “+”
R	1, 2, 3, or 5	Date/Lot or Serial Number Reference Identifier Numeric: If the first character is numeric, then R is a fixed 5-digit Julian date. No Lot/Batch or Serial Number is present (See Note 2) \$: If the first character is a “\$” and the second character is alphanumeric, then the Date fields are not used. \$\$: If the first two characters are “\$\$” followed by a digit, then the digit specifies the Date Field format. For use with lot numbers, not serial numbers. \$\$\$+: If the first three characters are “\$\$\$” followed by digit, then the digit specifies the date field format. For use with serial numbers, not lot numbers. See Appendix E1.2 If the first character is a number then the 5-digit Julian Date format follows. This format is included for backward compatibility only. It is recommended that “\$\$7” be used to indicate a lot/batch.
D	0 or 4-9	Expiry Date Field, for use after the Reference Identifier (includes the date field format indicator).
B	0-18	Lot/Batch or Serial Number Field, Alphanumeric field. See Appendix E1.2
L	1	Link Character (Check Character from primary data field.) (See 2.2.1.1 for concatenation rule).
C	1	Modulo 43 Check Character (calculated from the above characters) See Appendix B2.0.

Note 1: The HIBC Secondary Data Structure is distinguished from the Primary Data Structure in that the Primary Data Structure has an alphabetic character following the HIBC Supplier Labeling Flag Character “+”, while the Secondary Data Structure has a numeric character or a “\$” following the HIBC Supplier Labeling Flag Character. See Appendices E and F for more information.

Note 2: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field “+\$\$\$”.

Note 3: Quantity is no longer included in the Secondary Data Structure as it had been in previous versions of the standard, but can be included as Supplemental Data. For more information on how to include Quantity as Supplemental Data see section 2.3.2.4.

2.2.1.1 Combining Primary and Secondary Codes in One Symbol when Using the HIBC LIC Format

When combining the Primary and Secondary Code into a single symbol (known as concatenation), a forward slash (/) is used as a delimiter between the primary and secondary data. In addition, the primary data Link Character, the plus (+) at the start of the secondary data, and the secondary data Link Character are omitted. Only one Check Character at the end of the symbol will be used which will check the entire data string.

For example:

+ A 9 9 9 1 2 3 4 5 / \$ \$ 5 200 0 1 5 1 0 X 3 3

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
\$\$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
3	3 is the Check Character

2.2.2 Secondary Data Structure in Electronic Data Interchange

For information about communicating Secondary Data in Electronic Data Interchange, refer to the HIBCC Electronic Data Interchange (EDI) Guidelines. When using the HIBC data formats in Electronic Data Interchange, the Check Character is not transmitted or stored in the database.

2.3 Additional Supplemental Data

Additional Supplemental Data can be added to the Secondary data string. It is strongly recommended that Additional Supplemental Data be used in the concatenated format and with 2D symbologies to reduce the risk of creating a linear bar code that may be too long for practical use. Additional Supplemental Data can be used when a manufacturer wishes to encode both lot number and serial number in the same symbol, date of manufacture, expiry date in the YYYYMMDD format, and/or quantity. Quantity must be the last field in supplemental data when used in conjunction with other supplemental data.

2.3.1 Data syntax

The Secondary Supplemental Data field is constructed with a "/" character followed by a Data Identifier (DI), followed by data. Multiple Secondary Supplemental data fields are possible. The Secondary Supplemental Data will always follow the Secondary data, and the check character will be inserted at the end of the total string.

2.3.2 Data usage

2.3.2.1 Serial number when Lot number is used

For example, when serial number is encoded with the DI "S" using the following format.

Field Length - an1 + an18 S Serial number or code assigned by the Supplier to an entity for its lifetime, (e.g., computer serial number, traceability number, contract tool identification)

2.3.2.2 Date of Manufacture

Date of Manufacture is encoded with DI "16D" using the following format.

Field Length - an3+n8 16D Production Date (YYYYMMDD) – Date of manufacture

2.3.2 Example of HIBC data string with Secondary Supplemental Data

Following is an example with both a Date of Manufacture and a serial number added to a HIBC Primary and Secondary symbol containing a lot number and an expiry date.

+A99912345/\$\$52001510X3/16D20111212/S77DEFG457

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
\$\$5	Exp Date Flag
20015	Expiry Date is 15 day of year 2020 (15 January 2020) in the YYJJJ format (Julian Date format)
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111212	December 12, 2011
/	Secondary Supplemental Data delimiter
S	Serial Number Data Identifier
77DEFG45	serial Number
7	7 is the Mod 43 Check Character

2.3.2.3 Expiry date formatted as YYYYMMDD

Where a manufacturer wishes to use an expiry date with the format YYYYMMDD, which is not one of the available options in the secondary data formats, the manufacturer can instead use the supplemental data option for expiry date.

When using the supplemental data option the expiry date is encoded with DI "14D" using the following format.

Field Length - an3+n8 14D Expiry Date (YYYYMMDD) – Date of expiry

Following is an example with both a Date of Manufacture and the expiry date are added to a HIBC Primary and Secondary symbol containing a lot number only.

+A99912345/\$10X3/16D20111231/14D202001313

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
5	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
\$	Flag to indicate that Lot number only in secondary data
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111231	December 31, 2011
/	Secondary Supplemental Data delimiter
14D	Expiry Data Identifier
20200131	January 31, 2020
3	3 is the Mod 43 Check Character

2.3.2.4 Quantity

Where a manufacturer wishes to include quantity they shall use the supplemental data option for quantity.*

When using the supplemental data option the quantity is encoded with DI "Q" using the following format.

Field Length - an1+n1...n5 Q Quantity

Following is an example with a Date of Manufacture, YYYYMMDD expiry date, and quantity added to a HIBC Primary and Secondary symbol containing a lot number only.

+A99912345/\$10X3/16D20111231/14D20200131/Q500V

Where:

+	HIBC Supplier Labeling flag
A999	LIC
1234	Product ID
9	Unit of Measure
/	Data delimiter (to separate the primary from secondary data)
\$	Flag to indicate that Lot number only in secondary data
10X3	Lot Number
/	Secondary Supplemental Data delimiter
16D	Date of Manufacture Data Identifier
20111231	December 31, 2011
/	Secondary Supplemental Data delimiter
14D	Expiry Data Identifier
20200131	January 31, 2020
/	Secondary Supplemental Data delimiter
Q	Quantity Identifier
500	Quantity
Z	Z is the Mod 43 Check Character

*Note: Quantity is an optional field and should only be used with the Unit of Measure "9" for packages containing variable quantities.

3.0 Label Symbolologies

It is possible for a Primary (or a Primary and Secondary) Label to be encoded in one of two possible linear bar code symbologies, or alternatively in one of the approved 2D symbologies.

No special characters (-, ., \$, /, +, %, and space) are used in the Primary data structure other than the use of the flag characters, “+” and “\$”, in the beginning of the HIBC LIC symbols. The use of the special characters “.” and “-” are permitted in the Secondary data structure. Note that the generated Check Character may, however, be one of these special characters, including space. In addition, when combining both Primary and Secondary information in a single barcode, the “/” character is used as a concatenation character. (See section 2.2.1.1 for use).

The data structure and human-readable interpretation is identical regardless of symbology used.

See Appendix C for detailed printing information.

Specifications for these symbologies are available <http://www.ansi.org> and <http://www.iso.org>.

3.1 HIBC LIC Primary and/or Secondary Data – Linear Symbologies

Where a labeler decides to use a linear symbology, the labeler may use either of the linear symbologies in this section as directed.

- **Code 128:** HIBC primary and secondary data should be printed in separate Code 128 symbols but may be concatenated if space allows. More information on this symbology may be obtained from *ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification*.
- **Code 39:** HIBC primary and secondary data should be printed in separate Code 39 symbols but may be concatenated if space allows. More information on this symbology may be obtained from *ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification*.

If Code 39 is used, the Regular setting (not Full ASCII) should be used. In addition, the full ASCII function shall be disabled in the reader. The wide to narrow ratio should be 3:1, the inter-character gap should be equal to the nominal narrow element dimension (X-dimension) and the optional Mod 43 symbology Check Character is used.

3.2 HIBC LIC Primary and/or Secondary Data – 2D Symbologies

Where a labeler decides to use a 2D symbology, the labeler may use any one of the 2D symbologies in this section. When using a 2D symbol, a single 2D code should be used to carry all Primary, secondary and supplemental HIBC data as required. For example, those requiring the use of Primary and Secondary data structures should concatenate both into a single 2D symbol (See section 2.2.1.1 for concatenation mechanism).

- **Aztec Code:** HIBC data should be printed in a single Aztec Code symbol. More information on this symbology may be obtained from *ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification*.
- **Data Matrix ECC200:** HIBC data should be printed in a single Data Matrix ECC200 symbol. More information on this symbology may be obtained from *ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification*,
- **QR Code:** HIBC data should be printed in a single QR Code symbol. More information on this symbology may be obtained from *ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification*

4.0 Label Features

HIBC Guidelines provide information on printing techniques, symbol placement, and symbol orientation.

See Section 5 for print quality requirements and Appendix C for specific 2D symbol rules, guidance and examples

4.1 Human-Readable Interpretation

References are made to the Human Readable Interpretation of the bar code or auto-ID symbol in this standard. This refers to the text representation of the data in the bar code or auto-ID symbol that can be displayed underneath the bar code or auto-ID symbol. For example:



On product labels or packaging for medical devices, the generally accepted convention for displaying “plain-text” information is by using the symbols as shown in the example below:



2016-09-30 (to indicate the expiry date of September 30, 2016)



2010-09-30 (to indicate the manufacture date)



16390082 (to indicate the lot number)

All product marking including marking required by law shall be printed on the package in a legible font in an area which does not intrude into the symbol region, including quiet zones, and shall not affect the scannability of the symbol.

The following are meant as guidance, and in no case are to be meant to replace appropriate regulations.

The preferred human-readable interpretation of a HIBC Supplier Labeling linear Symbol is a line of characters, preferably directly underneath the bar code symbol, representing all encoded characters. The human-readable interpretation is intended to be used for human recognition only, and not as a method of machine readability addressed in this standard.

It is the recommendation of HIBCC that the human-readable interpretation of zero be represented as “Ø”. The Check Character or Link Character in the symbol will sometimes be a space character. In this case, the human-readable interpretation shall use an “underscore” to represent the space character. See Appendix B.2.1 for further guidance.

While the asterisk, “*” is not encoded within the barcode symbols, the human-readable interpretation for both HIBC LIC Primary and Secondary linear symbols should be bounded in the beginning and at the end of the data string by an asterisk, “*”.

The recommended human-readable format for the linear HIBC LIC Primary and Secondary Symbol should always enclose the human-readable data with the “*” regardless of symbology and should be phased in if possible, but previously designed labels will remain acceptable indefinitely.

4.2 Label Placement

Transport package labels should be placed no closer than 1.25 inches (3.2 cm) from any package edge, and the bottom edge of the label should be within the range of 1.25 inches to 3.0 inches (3.2 cm to 7.6 cm) from the natural bottom of the package.

4.3 Bar Code Symbol Examples

Examples of formats and printed symbols are shown below

4.3.1 HIBC LIC Primary Data Structure

Shown below are examples of the symbols for the HIBC LIC Primary Data Structure.



Figure 1. Code 128

Note: the figures in this document are here as examples only, and due to the nature of the document their resolution may not conform to the specifications that are needed when using these symbols in a working environment



Figure 2. Code 39



Figure 3 Data Matrix

4.3.2 HIBC LIC Secondary Data Structure

Shown below are examples of the symbols for the HIBC LIC Secondary Code Data Structure. They are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is G, and the Check character in the example below is D.

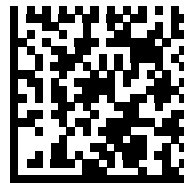


Figure 5. Code 128



Figure 6. Code 39

4.3.3 HIBC LIC Concatenated Primary and Secondary Data in a 2D Symbol



***+A123BJC5D6E71/
\$52001510X3C***

Note: the 2D concatenated symbol does not contain either check character of the primary symbols but rather has a new check character for the entire data string. The link character is not included in the concatenated symbol.

5.0 Print Quality

5.1 Code 128 or Code 39

The bar code symbol quality for a Code 128 or Code 39 symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols*. Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.010 inches (0.25 mm). Those labelers with high-resolution printing capability may utilize X-dimensions as low as 0.0067 inches (0.17 mm) providing the print quality requirements are met.

Any X-dimension greater than 0.0067 inches is allowable if the print quality requirement is met. The height of the bars should be at least 15% of the symbol length. Quiet Zones should be at least 10 times the X-dimension.

5.2 Aztec Code, Data Matrix or QR Code

The bar code symbol quality for an Aztec Code, Data Matrix or QR Code symbol in its final configuration shall be no lower than a C/06/660 when measured according to *ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols*. Labelers should attempt to reach B/06/660 or better at the time of printing.

Labelers should use an X-dimension of 0.015 inches (0.37 mm). Any X-dimension greater than 0.010 (0.25mm) inches is allowable if the print quality requirement is met.

6.0 Radio Frequency Identification (RFID)

HIBCC has produced a Guideline for RFID – *Using HIBC Standards with RFID: An Implementation Guideline*, which is a specification of the coding schemas required for RFID tagging using the HIBCC standards. This guideline is available from HIBCC, and can be downloaded from the HIBCC website www.hibcc.org.

Appendix A – Julian Calendar

Table A1

DAY OF MONTH	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
1	001	032	060	091	121	152	182	213	244	274	305	335
2	002	033	061	092	122	153	183	214	245	275	306	336
3	003	034	062	093	123	154	184	215	246	276	307	337
4	004	035	063	094	124	155	185	216	247	277	308	338
5	005	036	064	095	125	156	186	217	248	278	309	339
6	006	037	065	096	126	157	187	218	249	279	310	340
7	007	038	066	097	127	158	188	219	250	280	311	341
8	008	039	067	098	128	159	189	220	251	281	312	342
9	009	040	068	099	129	160	190	221	252	282	313	343
10	010	041	069	100	130	161	191	222	253	283	314	344
11	011	042	070	101	131	162	192	223	254	284	315	345
12	012	043	071	102	132	163	193	224	255	285	316	346
13	013	044	072	103	133	164	194	225	256	286	317	347
14	014	045	073	104	134	165	195	226	257	287	318	348
15	015	046	074	105	135	166	196	227	258	288	319	349
16	016	047	075	106	136	167	197	228	259	289	320	350
17	017	048	076	107	137	168	198	229	260	290	321	351
18	018	049	077	108	138	169	199	230	261	291	322	352
19	019	050	078	109	139	170	200	231	262	292	323	353
20	020	051	079	110	140	171	201	232	263	293	324	354
21	021	052	080	111	141	172	202	233	264	294	325	355
22	022	053	081	112	142	173	203	234	265	295	326	356
23	023	054	082	113	143	174	204	235	266	296	327	357
24	024	055	083	114	144	175	205	236	267	297	328	358
25	025	056	084	115	145	176	206	237	268	298	329	359
26	026	057	085	116	146	177	207	238	269	299	330	360
27	027	058	086	117	147	178	208	239	270	300	331	361
28	028	059	087	118	148	179	209	240	271	301	332	362
29	029	*	088	119	149	180	210	241	272	302	333	363
30	030		089	120	150	181	211	242	273	303	334	364
31	031		090		151		212	243		304		365

The HIBC Supplier Labeling Standard Format for use of Julian dating includes the last two digits of the year followed by a three-digit day-of-the-year code. For example, November 7, 1994 is represented as “94311” (the 311th day of 1994).

*A leap year has 366 days with February having 29. Julian dating in leap years is the same through February 28 (059) with February 29 as 060. All dating from March 1 through December 31 is incremented by one during leap years.

Appendix B – Check Character Calculation

B.1.0 Check Character Calculation

Be sure to use the Modulo 43 calculation when using the HIBC LIC data structures regardless of the symbology used.

B.2.0 HIBC LIC Check Character Modulo 43 Generator

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk “*” characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation. Check Character generation is illustrated by the following example with the table below:

Supplier Labeling Data Structure: + A 1 2 3 B J C 5 D 6 E 7 1
Sum of values: $41+10+1+2+3+11+19+12+5+13+6+14+7+1 = 145$

Divide 145 by 43. The quotient is 3 with a remainder of 16. The Check Character is the character corresponding to the value of the remainder (see table below), which in this example is 16, or “G”. The complete Supplier Labeling Data Structure, including the Check Character, would therefore be:

+ A 1 2 3 B J C 5 D 6 E 7 1 G

**Table of numerical value assignments for computing
the HIBC LIC data format Check Character**

Table B1

0 = 0	F = 15	U = 30
1 = 1	G = 16	V = 31
2 = 2	H = 17	W = 32
3 = 3	I = 18	X = 33
4 = 4	J = 19	Y = 34
5 = 5	K = 20	Z = 35
6 = 6	L = 21	- = 36
7 = 7	M = 22	. = 37
8 = 8	N = 23	Sp = 38
9 = 9	O = 24	\$ = 39
A = 10	P = 25	/ = 40
B = 11	Q = 26	+ = 41
C = 12	R = 27	% = 42
D = 13	S = 28	
E = 14	T = 29	

Note: The character corresponding to 36 is a dash or minus sign (ASCII decimal 45). The character corresponding to 37 is a dot or period (ASCII decimal 46). The character corresponding to 38 is a space (ASCII decimal 32).

B.2.1 Space Character Caution

The HIBC-LIC Check/Link character is **never** part of the **data message**. As such it should not normally be stored in a database or transmitted via EDI. It should be stripped away after the check and link functions have been executed. One of the possible values of the Check/Link Character is a space character (value 38). Although not recommended, if the link character must be stored or transmitted, the space character should be stored or transmitted explicitly as ASCII decimal 32 (ASCII Hex '20'). Note that some legacy systems and or software are unable to receive and or interpret trailing spaces as part of a data message.

Appendix C – Printing and Scanning Considerations

C.1 Printing Plates

Often, source printing requires the generation of a printing plate. Care should be given to produce the printing plate with smaller bars to compensate for ink spread. When “bar width reduction” or “X-dimension width reduction” is implemented, be sure that the spaces are enlarged by the same amount that the bars are reduced. The print quality requirement must be met on the final printed symbol. The printing plate can be fabricated using any method or accuracy as long as the final printed symbol meets the above specification.

C.2 Scanning Considerations

Scanners have different capabilities, be sure to match your scanner with your proposed symbol.

C.3 Example Symbols - Primary Data Structure

Example Data Structure:

+H123ABC01234567890D

Aztec Code

0.19" wide, 0.19" high
15 mil cell size, 19 x 19 matrix



Figure C1 Aztec Code

Data Matrix ECC200

0.18" wide, 0.18" high
15 mil cell size, 18 X 18 matrix

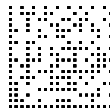


Figure C2 Data Matrix ECC200

QR Code

0.21" wide, 0.21" high
15 mil cell size, 21 X 21 matrix



Figure C5 QR Code

Appendix D – Reference Definitions

For the purposes of printing the HIBC Supplier Labeling Symbol, the following informative definitions are included for convenience.

D.1 Bars

The black or darker areas of the bar code symbol.

D.2 HIBC

Health Industry Bar Code.

D.3 HIBCC

HIBCC (Health Industry Business Communications Council) is the organization responsible for the development and maintenance of standards and services for use in the health care industry. HIBCC standards and information on its services, including the HIN System, Unique Device Identification (UDI) and other ecommerce applications are available from HIBCC at: 2525 E Arizona Biltmore Circle, Suite 127, Phoenix, Arizona. The telephone number for HIBCC is 602-381-1091. Fax: 602-381-1093. [Email: info@hibcc.org](mailto:info@hibcc.org) Web site: <http://www.hibcc.org>.

D.4 Quiet Zone

An area free of printing, preceding and following all linear bar code symbols and surrounding 2D symbols, that is required for the decoding process. The quiet zones for Code 128 and Code 39 are at least ten times the X-dimension in size.

D.5 Scannability

A general term describing the property of a bar code symbol whereby an attempt to use bar code reading hardware is successful. Symbols that meet ISO/IEC 15415 and ISO/IEC 15416 with a print quality level of C/06/660 generally will be scannable with a broad range of hand held bar code reading hardware.

D.6 Spaces

The white or lighter areas of the bar code symbol including the quiet zones.

D.7 Symbology

A set of rules for encoding information in a bar code symbol.

D.8 Unit-of-Use

A packaging level containing the item (the each) that is to be individually administered in a health care provider facility.

D.9 X-Dimension

The intended width of the narrow bar and narrow space in a bar code symbol.

Appendix E – HIBC Secondary Data Fields

E1.0 HIBC LIC Secondary Data Field

Appendix E describes the Secondary Data Formats with some examples. See Appendix F for a complete listing of Secondary Data Format options.

E1.1 Date Fields

These examples are based on the primary message in example 4.3.1, +A123BJC5D6E71G. In this case, the Link character ('L' in table 2) is "G". Check characters have been calculated for these examples.

If the character following the leading "+" is a "\$" but the next character is alphanumeric, then the Date Field is null, and the character following the "\$" is the first character in the Lot/Batch Number.

For example:

+ \$ A 1 2 3 4 G U *Lot # is A1234*

If there is a two character lot number flag "\$\$", or a three character serial number flag "\$\$+", following the leading "+", then the first digit following will specify the Date Field formats:

The digits 0 through 7 specify the Date Format:

- 0, 1 First digit of month in MMY (month/year) Date format
- 2 MMDDYY (month/day/year) Date follows
- 3 YYMMDD (year/month/day) Date follows
- 4 YYMMDDHH (year/month/day/hour G.M.T.) Date follows
- 5 YYJJJ (year/Julian day) Date follows
- 6 YYJJJHH (year/Julian day/hour G.M.T.) Date follows
- 7 Date Field is null, Lot Field follows

E1.2 Lot/Batch and or Serial Number Field

The Lot/Batch or Serial Number field can be alphanumeric and vary in length up to a maximum of 18 characters. If the field is not required (because neither Lot/Batch nor Serial Number is desired), the field should be null. The string header +\$\$ is used for Lot/Batch cases, with +\$\$+ being used exclusively for Serial Number implementations.

E1.3 Link Character

The Link Character is intended to link the Primary and Secondary Code Data Structures when encoded in separate linear symbols. The Link Character for the Secondary Data Structure is the last character from the Primary Data String in the Primary Symbol (Check Character). The Link Character is not included in concatenated data structures.

Appendix F – Data Formats for HIBC Secondary Bar Codes

The following tables show the correct data formats for HIBC secondary bar codes. If a column is left blank, then that information is not used. The following field descriptions are used:

MM	2 digit expire date month indicator (fixed length of 2 numeric digits)
YY	2 digit expire date year indicator (fixed length of 2 numeric digits)
DD	2 digit expire date day indicator (fixed length of 2 numeric digits)
HH	2 digit expire date hour indicator (fixed length of 2, G.M.T. format)
JJJ	3 digit expire date Julian Day indicator (fixed length of 3 numeric digits)
LOT	up to 18-digit alpha/numeric lot/batch number
S/N	up to 18-digit alpha/numeric serial number
L	Link Character
C	Modulo 43 Check Character

The following example data is always used in table F1:

Lot Number	3C001
Serial Number	0001
Link Character	L (Check Character from Primary Symbol)
Check Character	C (1 character Modulo 43 Check Character)
Expire	Date September 28, 2005 at 10 PM

The following are the secondary data formats. As stated before, when encoding in separate linear symbols, the link character 'L' is the last character from the primary data string. If the primary message were +A123BJC5D6E71G as in example 4.3.1, the link character 'L' would have a value of 'G'. The Check Character 'C' has not been calculated in these examples.

Table F1

HIBCC Qty Flag	Exp Date Flag	Exp Date Format	Lot/Batch Field	Serial Number Field	Link Char	Mod 43 Ck Char	Example Data
+		YYJJJ	Note 1		L	C	+05271LC
+\$			LOT		L	C	+\$3C001LC
++\$		MMYY	LOT		L	C	++\$09053C001LC
++\$	2	MMDDYY	LOT		L	C	++\$20928053C001LC
++\$	3	YYMMDD	LOT		L	C	++\$30509283C001LC
++\$	4	YYMMDDHH	LOT		L	C	++\$4050928223C001LC
++\$	5	YYJJJ	LOT		L	C	++\$5052713C001LC
++\$	6	YYJJJHH	LOT		L	C	++\$605271223C001LC
++\$	7		LOT		L	C	++\$73C001LC
++\$+				S/N	L	C	++\$+0001LC
++\$+		MMYY		S/N	L	C	++\$+09050001LC
++\$+	2	MMDDYY		S/N	L	C	++\$+20928050001LC
++\$+	3	YYMMDD		S/N	L	C	++\$+30509280001LC
++\$+	4	YYMMDDHH		S/N	L	C	++\$+4050928200001LC
++\$+	5	YYJJJ		S/N	L	C	++\$+5052710001LC
++\$+	6	YYJJJHH		S/N	L	C	++\$+605271200001LC
++\$+	7			S/N	L	C	++\$+70001LC

Note 1: Earlier versions of this standard permitted an optional variable length (0 to 13) alphanumeric lot/batch field to follow the five-digit Julian date field (for example +YYJJJDDDDDDDDDDDDLC). Software that interprets encoded HIBCC secondary data fields should allow lot/batch data following the fixed-length numeric Julian date. Users who wish to encode a five-digit Julian date followed by a lot/batch field should use the current format of the secondary data field "++\$5".

Note 2: Secondary Supplemental Data can be included in the data string by the following the rules defined in Section 2.3.

Appendix H – Backward Compatibility

Every effort has been made to insure this standard is backwardly compatible. Some infrequently used aspects of the previous standard were dropped or replaced. Among these is the use of quantity in the secondary data structure. From this point forward labelers that wish to include quantity will do so in the supplemental data field as indicated in section 2.3.2.4 of this document. Existing labels are still valid, but should not be used for Unique Device Identification (UDI).

References to ISO/IEC 15434 and ANS MH10.8.2 have been removed from this document. For more information refer to the previous standard or ISO/IEC 15434 and ANS MH10.8.2 directly.

Appendix I – Bibliography

ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols

ISO/IEC 15417 Information technology -- Automatic identification and data capture techniques -- Code 128 bar code symbology specification

ISO/IEC 16022 Information technology -- Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

ISO/IEC 16388 Information technology -- Automatic identification and data capture techniques -- Code 39 bar code symbology specification

ISO/IEC 18004 Information technology -- Automatic identification and data capture techniques -- QR Code bar code symbology specification

ISO/IEC 24778 Information technology -- Automatic identification and data capture techniques -- Aztec Code bar code symbology specification

ISO/IEC 29158, Information technology – Automatic identification and data capture techniques – Direct Part Mark (DPM) Quality Guideline

ANS MH10.8.2-2006 American National Standard – Data Identifier and Application Identifier Standard

The above International Standards can be obtained at either <http://www.ansi.org> or <http://www.iso.org>

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Subject: application for IAC

The Registration Authority of ISO/IEC 15459 has reviewed the application Health Industry Business Communications Council (HIBCC) d.d. June 12, 2008 for issuing agency under ISO/IEC 15459 - *Information Technology - Unique Identification of Transport Units* and subsequent information submitted by Health Industry Business Communications Council (HIBCC).

The Registration Authority has concluded that the application meets the approval criteria set out in ISO/IEC 15459-2, except for clause 4.2.2.e) (payment of fee) and has provisionally registered an Issuing Agency Code (IAC). The allocation and registration will be confirmed after receipt of the registration fee and applies for a period of 2 year.

You will receive an invoice for the registration fee of EUR 400,- (excl. VAT) separately.

The IAC value allocated Health Industry Business Communications Council (HIBCC) is indicated on the enclosed copy of the application form.

May I draw your special attention to the responsibilities allocated by ISO/IEC 15459 to Issuing Agencies and the adherence of your organisation, and of organisations authorised by Teikoku Databank Ltd., to these rules and to the rules of ISO/IEC 15418 when use is made of the IAC in an open environment. These are essential to safeguard the integrity of the methodology and the uniqueness of license plates.

If we do not receive the registration fee within a period of 4 months, we will assume that the registration is not longer of interest to your organisation and we will cancel the provisional registration.



[DATE]

Mr. [Contact Name at Company], [Title, if available]
[Company Name]
[Address Line 1]
[Address Line 2]

Re: HIBCC Labeler Identification Code (LIC)

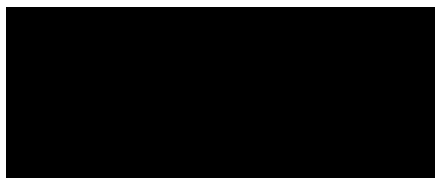
Dear [Contact Name at Company]:

It has recently come to our attention that [Company Name] is using an altered or incorrect LIC. HIBCC-Registered Labelers are required to use the Labeler Identification Code (LIC) assigned by HIBCC only in barcodes that conform to the HIBC Supplier Labeling Standard (SLS). The LIC is not intended to be a stand-alone identifier, but is a component of the HIBC SLS and/or the FDA required UDI. Labelers are not permitted to alter their LIC in any way.

The LIC may only be used by the entity listed on the labeler's original application. In the event that the labeler must change the contact information and/or company name associated with the original application, the labeler must complete the LIC Change Form (located on HIBCC website) and return to HIBCC.

Your reply in this matter is expected within 30 days of the date of this letter. If action is not taken within 30 days of receiving this letter, HIBCC will remove [Company Name] from our list of labelers and the FDA will be notified. Should you have any questions please feel free to contact our office.

Sincerely,



President & CEO

RAH/cam

cc: Person's Name, Legal Department
HIBCC Legal Department



**American National
Standards Institute**

11 WEST 42ND STREET, NEW YORK, NEW YORK 10036

TEL. 212.642.4900

FAX. 212.398.0023

Cable: Standards, New York

International Telex: 42 42 96 ANSI UI

D-U-N-S 07-329-4837

July 12, 1995

[REDACTED]
President

Health Industry Business Communications Council

5110 N. 40th Street, Suite 250

Phoenix, AZ 85018

[REDACTED]

On behalf of the Executive Standards Council, I am pleased to inform you that the accreditation of Health Industry Business Communications Council using the Organization method, has been approved effective July 11, 1995.

I wish to take this opportunity to call your attention to Clause 4 of the *ANSI Procedures for the Development and Coordination of American National Standards (ANSI Procedures)* which covers the designation, publication and maintenance of American National Standards. Should you have any questions concerning these requirements, please do not hesitate to contact me.

The staff person who will be responsible for this activity is Mr. Steven Cornish. Please do not hesitate to contact him at (212) 642-4969 if you have any questions.

Sincerely,

[REDACTED]

HIBC solution for EU MDR/IVDR Basic UDI-DI

European Medical Device regulation (1) and In-Vitro Diagnostica regulation (2) defines the Basic UDI-DI for the Eudamed Data Base and for the Certificates issued by Notified Bodies.

The Basic UDI-DI is constructed by the device manufacturer following the rules of the accredited issuing agencies. This document is describing the construction rules for Basic UDI-DI of the issuing agency for HIBC.

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2. Abbreviated terms and mathematical/logical notations

This chapter lists the abbreviated terms and mathematical notations of this document.

2.1. Abbreviated terms

Basic UDI-DI Unique ID for a set of physical devices/packages (e.g. set of PCN numbers)

HIBC	Health industry business code (3).
IAC	Issuer Agency Code. A code prefix given to an issuing agency (synonym: issuing entity) to generate unique numbers (4).
LIC	Labeller issuer code. This code is a unique identifier for medical device labelers issued by the HIBC issuing entity.
PCN	Abbreviation for "Product or Catalog Number". This is the field in the UDI-DI describing the physical product/package. The PCN may be chosen to be identical to the REF (3).
BDN	Basic UDI-DI Device Number. The subfield of Basic UDI-DI chosen by the manufacturer.
REF	Abbreviation for "Reference number". The REF is an identifier for physical devices/packages of the same type.
UDI-DI	Unique identifier for physical devices/packages of the same type. This is often directly linked to the REF number.

2.2. Mathematical notations

mod is the integer remainder after division. 13 mod 2 is 1: 13 divided by 2 gives 6 remainder 1.

3. What is a Basic UDI-DI?

The Basic UDI-DI is grouping a set of physical devices/packages and establishes a link to the relevant certificate issued by the notified body. Thus, It is defined for use in the Eudamed database and on device certificates issued by notified bodies.

The Basic UDI-DI is assigned by the device manufacturer following the rules of issuing entities.

The manufacturer creates one descriptive device record per Basic UDI-DI in the Eudamed Device UDI module.

Each physical device has a UDI on its label, which is referencing to a Basic UDI-DI within its record in the Eudamed UDI module. Each entry in the UDI module of Eudamed references one Basic UDI-DI.

The Basic UDI-DI is not printed on the device label.

4. HIBC rules for Basic UDI-DI

4.1. Structure

Basic UDI-DI values are created by the LIC-holder. The Basic UDI-DI consists of the following fields being concatenated:

Abbreviation	Name	Format	Example	Description
IAC	Issuing Agency Code	0..3 alphanumerics	RH	Issuing agency code for the issuer as defined by . ISO/IEC 15459 (4).
LIC	Labeler Issuer Code	1 alpha + 3 alphanumeric	E999	Labeler Issuer Code. This unique labeler identification code is assigned by the issuing agency.
BDN	Basic UDI-DI Device Number	1 to 20 alphanumerics plus special characters "-.,;,\$%&()=?+ #<>" The HIBC field separator "/" and space " " is explicitly omitted.	AQ7B5	Basic UDI-DI issued uniquely by the LIC-holder. ¹
Check	Modulo43 check digits	1 alphanumeric plus special characters "-.,;,\$%&()=?+ #<>" and the space character " "	F	Check digits calculated from the concatenated fields IAC, LIC and BDN

4.2. Check Digits calculation following the modulo 43 algorithm

The last two digits of the Basic UDI-DI string are the Check digits calculated from all preceding characters following the modulo97 algorithm as described below:

Each of the HIBC LIC Standard data structures employs a Modulo 43 Check Character for additional data security. The Check Character is the Modulo 43 sum of all the character values in a given message, and is printed as the last character in a given message, preceding the Stop Character. Leading and trailing asterisk "*" characters in the human-readable interpretation are not used in calculating the Check Character and are only represented in the human-readable interpretation. Check Character generation is illustrated by the following example with the table below:

Char	R	H	E	9	9	9	A	Q	7	B	5
Numerical Assignments	27	17	14	9	9	9	10	26	7	11	5
Sum of Products	27 + 17 + 14 + 9 + 9 + 9 + 10 + 26 + 7 + 11 + 5 = 144										
Modulo 43	144/43 = 3 with a remainder of 15. The remainder is the Mod 43 check sum. 15 = F										

Divide 145 by 43. The quotient is 3 with a remainder of 15. The Check Character is the character corresponding to the value of the remainder (see table below), which in this example is 15, or "F". The complete Basic UDI-DI, including the Check Character, would therefore be:

RHE999AQ7B5F

¹ Within a draft MDCG document, the Basic-UDI DI length is limited to 25 characters. In consequence, the field BDN is limited to 17 characters.

**Table of numerical value assignments for computing
the HIBC LIC data format Check Character**

Table B1

0 = 0	F = 15	U = 30
1 = 1	G = 16	V = 31
2 = 2	H = 17	W = 32
3 = 3	I = 18	X = 33
4 = 4	J = 19	Y = 34
5 = 5	K = 20	Z = 35
6 = 6	L = 21	- = 36
7 = 7	M = 22	. = 37
8 = 8	N = 23	Sp = 38
9 = 9	O = 24	\$ = 39
A = 10	P = 25	/ = 40
B = 11	Q = 26	+ = 41
C = 12	R = 27	% = 42
D = 13	S = 28	
E = 14	T = 29	

Note: The character corresponding to 36 is a dash or minus sign (ASCII decimal 45). The character corresponding to 37 is a dot or period (ASCII decimal 46). The character corresponding to 38 is a space (ASCII decimal 32).

4.3. Uniqueness to Basic UDI-DI issued by other issuing entities

The Issuing agency code is used as a prefix to get world unique codes issued by different issuing agencies.

The definition of the GS1 Global Model Number GMN (6) is following this rule, as the GS1 issuing agency code is 0 to 9.

4.4. Uniqueness of Basic UDI-DI and UDI-DI

Basic UDI-DI and UDI-DI should not overlap.

This condition is fulfilled if no LIC code starts with "RH". This is the case as those codes are not issued.

4.5. Basic UDI-DI Device Number

Each manufacturer may use the BDN field to create a Basic UDI-DI according his numbering scheme.

There are no rules implied of the construction of this field other than the character set of the BDN.

Nevertheless, the following strategies may be considered on a company level:

- Choose the Basic UDI-DI Device Number field as the certificate number plus a number to identify the device covered by the certificate.
- Choose the Basic UDI-DI equal to the UDI-DI PCN field, if there is a 1:1 relationship (3).
- Choose a device document number from the life-cycle management system of the manufacturer, which is unique within the companies domain.

The upper possibilities may be used as a mixed setup as long as uniqueness is maintained.

4.6. Example

The example values given in the upper table result in the final Basic UDI-DI value:

RHE999AQ7B5F

This number is constructed by the concatenation of the fields IAC, LIC and BDN and by the addition of the check digits calculated from the preceding fields.

5. Literature

1. **European_Union.** EU Medical Device Regulation 2017/745. [Online] 2017. <http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC>.
2. —. EU In-Vitro Diagnostica Regulation 2017/846. [Online] 2017. <http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=OJ%3AL%3A2017%3A117%3ATOC>.
3. **HIBCC.** ANSI HIBC 2.6 Supplier Labeling Standard. [Online] 2016. <http://www.hibcc.org/udi-labeling-standards/barcode-standards/>.
4. **ISO/IEC.** *ISO/IEC 15459-2:2015 Information technology -- Automatic identification and data capture techniques -- Unique identification -- Part 2: Registration procedures*. 2015.
5. —. *ISO/IEC 646:1991, Information technology — ISO 7-bit coded character set for information exchange*. 1919.
6. **GS1.** GS1 General Specifications. [Online] January 2018. <https://www.gs1.org/barcodes-epcrfid-id-keys/gs1-general-specifications>.



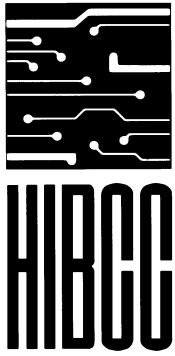
Policy for Use of the HIBCC Standard

HIBCC-Registered Labelers are required to use the Labeler Identification Code (LIC) assigned by HIBCC only in barcodes that conform to the HIBC Supplier Labeling Standard(SLS). The LIC is not intended to be a stand-alone identifier, but is a component of the HIBC SLS and/or the FDA and European Union required UDI. Labelers are not permitted to alter their LIC in any way.

The LIC may only be used by the entity listed on the labeler's original application. In the event that the labeler must change the contact information and/or company name associated with the original application, the labeler must complete the LIC Change Form (located on HIBCC website) and return to HIBCC.

If a HIBCC registered Labeler is found to be using an altered or incorrect LIC HIBCC will notify the labeler in writing. There after, the labelers will be removed from HIBCC's list of labelers and the FDA will be notified, unless the correction is made within 30 days.

For additional questions contact HIBCC at (602) 381-1091 or by email at info@hibcc.org



Health Industry Business Communications Council

MEETING GUIDELINES FOR ANTITRUST POLICY

The HIBCC policy for Technical/Advisory Committee meetings prohibits any discussions, which constitute or imply an agreement or understanding concerning:

- Prices, discounts, or terms or conditions of sale
- Profits, or profit margins or cost data
- Market shares, sales territories or markets
- Allocation of customers or territories
- Selection, rejection or termination of customers or suppliers
- Restricting the territory or markets in which a company may resell products
- Restricting the customers to whom a company may sell

or any matter which is inconsistent with the proposition that each member company of the HIBCC Technical/Advisory Committees must exercise its independent business judgement in pricing its services or products, dealing with its customers and suppliers and choosing the markets in which it will compete.

HIBCC Technical/Advisory Committee meetings shall be conducted pursuant to agendas distributed in advance to attendees; discussions shall be limited to agenda items; there shall be no substantive discussions of HIBCC Technical/Advisory Committee matters other than at official meetings; and minutes shall be distributed to attendees promptly following adjournment of each meeting.



**HEALTH INDUSTRY BUSINESS
COMMUNICATIONS COUNCIL
(HIBCC)**

**CONFLICT OF INTEREST POLICY
AND
STATEMENT OF ACCEPTANCE**

A. All officials (board members, officers, committee members) of the Health Industry Business Communications Council (HIBCC) shall scrupulously avoid conflicts – potential or real – between their own personal interests and those of HIBCC.

B. All officials of HIBCC have a fiduciary relationship with and owe a duty of loyalty to HIBCC. The fiduciary and loyalty obligations of officials require them to act on behalf of and for the benefit of HIBCC in all matters connected with or involving the interests of HIBCC. Therefore, it will be a conflict of interest and breach of the fiduciary and loyalty obligations for an official to:

- Actively solicit for or encourage a competitive venture;
- Fail or refuse to maintain and protect HIBCC's confidential, proprietary and/or trade secret information;
- Fail or refuse to assist, promote, encourage and, through the cooperative efforts of the officials, develop and advance the business and economic welfare of HIBCC.

C. Officials of HIBCC should not be financially interested or involved in any contract made by them in their official capacity or by the Board of Directors. Nor should said officials make sales to or purchases from this corporation or receive any compensation or fees for services to this corporation without the prior approval of the Board of Directors. Officials must disclose any direct financial interest or involvement in or with any matter coming before the board or committee.

D. Any official having a duality of interest or conflict of interest on any matter, (1) should make a full disclosure to the board, (2) should not vote or use personal influence on the matter, and (3) should be absent during the review and vote on the decisions in question. The minutes of the meeting should reflect that a disclosure was made, the abstention from voting, the absence

from the room during the review and vote. The foregoing requirements should not be construed as preventing the official from providing the board or committee with any and all relevant information known by the person having a conflict. When there is a doubt as to whether a conflict of interest exists, the matter shall be resolved by a vote of the Board of Directors or a committee, as the case may be, and the board member shall recuse him/herself from participating in the voting process.

E. Each official of HIBCC shall be given a copy of this conflict of interest policy and shall be required to disclose in writing any direct or indirect benefits each year, by no later than the close of HIBCC's fiscal year. This conflict of interest policy shall be reviewed periodically for the information and guidance, directors, officers and staff, and any new directors, officers, or staff shall be advised of the provisions of this policy upon undertaking the duties of such office.

I acknowledge receipt and have read the above Conflict of Interest Policy and I agree to abide by its provisions during my tenure as an official of HIBCC.

Signature: _____

Printed Name: _____

Date: _____

Health Industry Business Communications Council
STANDARD OPERATIONAL PROCEDURES
2016

1.0 TITLE

The name of the organization is the Health Industry Business Communications Council (HIBCC).

1.1 SCOPE

The primary function of HIBCC is to facilitate electronic communications by developing appropriate standards for information exchange among all health care trading partners.

1.2 RESPONSIBILITIES

HIBCC shall be responsible for developing proposed American National Standards (ANS) through the work of broad-based technical committees. The Auto-ID Technical Committee (AITC), and any subgroups created in accordance with these standard operating procedures, shall be responsible for developing, revising, re-affirming ANS and withdrawing ANS. Any substantive changes to ANS shall be referred to the AITC (the designated consensus body) for final approval (as indicated on the BSR-9). The HIBCC Board will provide oversight as designated herein, and will authorize by majority vote the submission to ANSI of the ANS. The HIBCC Board Chair shall serve as a voting member of the Committee. The HIBCC Board shall also have the right to approve the formation of additional technical committees as it deems necessary. HIBCC will maintain the standards in accordance with ANSI requirements and ensure that all requests for interpretation of the standard(s) are addressed according to the Interpretation Policy. In addition, all ANSI requirements for due process, criteria for accreditation and consensus will be met. HIBCC will ensure that the Standard(s) are periodically reviewed and continuously maintained. HIBCC will complete action (or request an extension of time) to revise, reaffirm or withdraw an ANS by the fifth year after the initial approval of the document as an ANS.

The HIBCC administrative office/secretariat shall organize technical committees, apply for committee accreditation by ANSI and maintain accreditation in accordance with ANSI requirements, including submission of the committee roster. In addition, HIBCC shall maintain a roster of the Committee and a list of the standards for which it is responsible. HIBCC shall provide a secretary to provide administrative work including secretarial services; meeting notices and arrangements; preparation and distribution of meeting agendas, minutes, ballots and draft standards; and maintenance of adequate records for each technical committee.

HIBCC shall submit candidate standards approved by the Committees and the HIBCC Board, with supporting documentation for ANSI review and approval as American National Standards and publish or arrange with ANSI for publication of its standards, revisions and addenda.

Any additional administrative functions as required by these procedures will be the responsibility of the HIBCC administrative office. These Standard Operating Procedures will be maintained by the HIBCC office and are subject to approval by a majority vote of the HIBCC Board. They will apply to the AITC, subgroups created by the AITC, as well as any other committees designated by the HIBCC Board.

2.0 OFFICERS

The HIBCC Chairman upon the approval of the HIBCC Board will appoint a chair and have the option of also appointing a co-chair for each Committee from the individual members of the Committee. Each will serve for one year and until a successor is selected and ready to serve. The co-chair shall carry out the chair's duties if the chair is temporarily unable to do so. Alternatively, a Committee secretary appointed by the HIBCC administrative office shall carry out the duties of the chair in the event of the absence of both the chair and a co-chair.

2.1 COMMITTEE PARTICIPATION

A request for representation on a Technical Committee shall be addressed to HIBCC and shall indicate the applicant's direct and material interest in the Committee's work, qualifications and willingness to participate actively, and, if the applicant is an organization, company or government agency, shall identify a principal (and an alternate, if desired) representative. All requests for Committee representation are subject to approval by the HIBCC Board and the Committee itself. Interested parties must attend two consecutive meetings as guests, in order to be considered for membership.

A modest annual registration fee is charged for each representative who attends Technical Committee meetings. Registration fees will be determined by the HIBCC Board and administered by the HIBCC Executive Office. It is not intended that the fees create undue financial barriers to participation. A request for a fee waiver may be made in writing to the HIBCC Executive office and will be considered based on individual circumstances.

2.2 RECOMMENDATION

In recommending appropriate action on applications for Committee representations, the HIBCC Board and Committee shall consider the following:

- Need for active participation by each interest;
- Potential for dominance by a single interest category;
- Extent of interest expressed by the applicant and the applicant's willingness to participate actively;
- The representative identified by the applicant organization, company or government agency.

The secretariat and/or HIBCC Board may consider reasonable limits on committee size.

2.3 DIVERSE INTERESTS

If distinct divisions of an organization can demonstrate independent interests and authority to make independent decisions with regard to the activity of the Committee, each may apply for Committee representation. If an interest is already represented on a Technical Committee, the secretariat may recommend that an applicant seek representation through the existing representative.

2.4 REVIEW OF COMMITTEE MEMBERSHIP

HIBCC shall review committee membership lists annually. Committee members are expected to fulfill obligations of active participation. When members are found in habitual default of these obligations, HIBCC shall direct the matter to the Committee chair and co-chair and/or the HIBCC Board for appropriate action, which may include termination of membership on the Committee.

2.5 OBSERVERS AND INDIVIDUAL EXPERTS

Individuals and organizations, having an interest in committee work may request listing as committee observers and will be subject to approval by the HIBCC Board. The Committee may also select individual experts to assist with Committee activities and deliberations. Individual experts shall serve for a renewable term of one year and shall be subject to approval by vote of the HIBCC Board. Observers and individual experts shall be advised of the Committee activities, may attend meetings, and may submit comments for consideration, but shall have *no* vote.

2.6 INTEREST CATEGORIES

All appropriate interests that might be directly and materially affected by the standards activity of HIBCC shall have the opportunity for fair and equitable committee participation without dominance by any single interest.

The standards development process shall not be dominated by any single interest category, individual or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.

The standards development process should also have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

Historically the criteria for balance are that a) no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

Each principal/alternate representative shall propose its own interest category as appropriate and in accordance with the Committee's established categories. Interest categories may include - user, producer and general interest as follows:

Healthcare Provider/User: Individual/Representative of healthcare facility or Organization using Auto-ID Technology.

Producer: Individual/Representative of Company or Organization manufacturing, distributing, producing or selling Auto-ID Technology.

General Interest: Individual/Representative of Company or Organization with a general interest in Auto-ID Technology and/or the Committee's work.

Interest categories shall be established or revised by a vote of the Committee upon recommendation by the HIBCC Board. The rationale for the selection of categories shall be included in the committee ballot and submitted to ANSI as part of the accreditation requirements.

2.7 MEMBERSHIP ROSTER

HIBCC shall maintain current Committee rosters and shall distribute them to the Committee representatives at least annually and otherwise on request. If changes are made to the roster, HIBCC shall redistribute it to all members.

The roster shall include the following:

- Title of the Committee and its designation;
- Scope of the Committee;
- Name of organization, secretary and addresses;
- Chair and co-chair of the Committee;
- Name, address and business affiliation of individual Committee member(s);
- Classification of each member;
- Tally of classifications: total of voting members and subtotals for each interest category;
- Title, name of chair and names and addresses of all members (including chair) of sub-groups if applicable.

2.8 TERMINATION OF MEMBERSHIP

Voting representation on the Committee shall be terminated upon failure to:

- 1) attend two out of three successive meetings, in which case the representation shall be terminated if not represented at the next meeting; or
- 2) respond to 80% of the total letter ballots (non-accelerated) closing during the current calendar quarter, in which case the representation shall be terminated if the member fails to respond to at least to the subsequent letter ballot; or
- 3) fulfill obligations of active participation per section 2.4 (i.e. habitual non-responsiveness to secretariat or Committee Chair, failure to complete assigned committee tasks in a timely manner, etc); or
- 4) pay all applicable committee representation registration, unless a fee waiver has been requested and granted.

The principal and all alternate representative(s) shall be notified in writing upon failure of the organization to meet any of the above conditions.

An organization and/or individual that has had their representation terminated may re-establish representation in accordance with 2.1 and 2.2. Under extenuating circumstance, the Committee or the HIBCC Board may vote to continue the representation despite failure of the member to comply with the representation criteria above.

2.9 RESIGNATION OF MEMBERSHIP

Resignation of membership in the Committee or any of its subgroups should be made in writing to HIBCC who will forward a copy to the appropriate Chair.

3.0 SUBGROUPS CREATED BY THE COMMITTEE

When one or more subgroups of a Technical Committee are formed, their formation (and later disbandment) requires approval by a majority vote of the Committee and the secretariat. The scope and duties delegated to the subgroup shall be outlined and approved at the time it is formed. Subsequent changes in scope or duties shall require additional approval. The charge to the subgroup shall clearly state in what way the subgroup is responsible for assisting the Committee (e.g. drafting all or a portion of a standard, drafting responses to comments, drafting positions on international standards, voting on approval of ANS revisions or re-affirmations, or other purely advisory functions.)

3.1 CHAIRPERSON AND MEMBERS OF SUBGROUPS

The chair and members of a subgroup shall be appointed by the chair of the Committee and confirmed by the Committee. The scope, duties, and membership of all subgroups shall be reviewed by the Committee annually. The chairs and members of a subgroup need not be members of the Committee.

4.0 APPROVAL OF STANDARDS

Draft standards and any substantive change in the content of a standard or withdrawal of a standard proposed by a subgroup shall be referred to the Committee for approval.

4.1 MEETINGS

Technical committee meetings shall be held, as decided upon by the Committee, the chair, the secretariat or by petition of five or more members, to conduct business, such as making assignments, receiving reports of work, considering draft standards, resolving differences among subgroups, and considering views and objections from any source. Meetings of subgroups may be held as decided upon by the members or chair of the subgroup.

4.2 OPEN MEETINGS

Technical Committee meetings shall be open to all parties having a direct and material interest. At least four weeks' notice of regularly scheduled meetings shall be given by the secretariat in ANSI's *Standards Action*; or in other media designed to reach directly and materially affected interests; or in both. The notice shall describe the purpose of the meeting and shall identify a readily available source for further information. An agenda shall be available and shall be distributed in advance of the meeting to members and to others expressing interest. The secretariat may optionally maintain a permanent mailing list of other interests.

5.0 QUORUM

The presence of 51% of members of the Committee shall constitute a quorum for conducting business at a meeting. If a quorum is not present, actions may be taken subject to confirmation by letter ballot.

6.0 VOTE

Each Committee member shall vote one of the following positions:

- Affirmative;
- Affirmative, with comment;
- Negative, with reasons (the reasons for a negative vote shall be given and if possible should include specific wording or actions that would resolve the objections);
- Abstain, with reasons.

6.1 VOTE OF ALTERNATE

An alternate's vote is counted only if the principal representative fails to vote.

6.2 SINGLE VOTE

Generally no Committee representative shall have more than one vote. However, if two or more organizations appoint the same individual to represent them, that individual may cast a separate vote for each organization represented. The organizations shall confirm in writing to the secretariat that they are aware of and will accept the results. Additionally, representation of more than one organization by the same individual shall require approval by a majority of the Committee, excluding the vote of that individual.

6.3 VOTING PERIOD

The voting period for letter ballots shall end two weeks from the date of issue or as soon as all ballots are returned, whichever comes earlier. An extension may be granted at the chair's option, when warranted. A follow-up letter requesting immediate return of the ballot shall be sent, as appropriate, to members and alternate members whose votes have not been received within five calendar days of the ballot close.

6.4 ACTIONS REQUIRING APPROVAL BY A MAJORITY OF COMMITTEE REPRESENTATIVES

The following actions require approval by a majority of the Committee representatives at a meeting or by letter ballot, excluding abstentions:

- Formation of a Committee subgroup, including its procedures, scope and duties;
- Disbandment of subgroups;
- Addition of new Committee members and designation of their interest categories.

The following actions, by Committee vote at a meeting, require approval by a majority of the members present:

- Approval of minutes;
- Authorization of a letter ballot (unless initiated per Section 6.7).

6.5 ACTIONS REQUIRING APPROVAL BY A MAJORITY OF THE HIBCC BOARD

The following actions require a letter ballot or an equivalent formal recorded vote with approval by at least a majority of the HIBCC Board, excluding abstentions:

- Adoption of Committee procedures, interest categories, or revisions thereto;
- Approval annually of Committee roster;

- Approval of change of Committee scope;
- Approval of termination of the Committee.

6.6 ACTIONS REQUIRING OPPORTUNITY FOR CONSIDERATION BY ENTIRETY

The following actions require the opportunity to cast a letter ballot or an equivalent formal recorded vote by all voting committee members and Board of Directors. Consensus within the Committee is required for all such actions:

- Approval of a new standard or reaffirmation and/or withdrawal of an existing one;
- Approval of revision or addendum to part or all of a standard.

All members of the Committee will be given the opportunity to vote on ANS related actions, even if they cannot attend a meeting (e.g. via follow-up confirmation ballot or the equivalent). Consensus will be determined by the majority voting rule (see Clause 6.8).

6.7 AUTHORIZATION OF LETTER BALLOTS

A letter ballot may be authorized by any of the following:

- Majority vote of those present at a meeting;
- The Chair;
- The HIBCC Executive Committee;
- The secretariat;
- Petition of five or more members of the Committee.

6.8 DEFINITION OF CRITERIA FOR APPROVAL

- **Majority**
For on-site, hand meeting votes, a majority is defined as approval by more than half of the members voting, excluding abstentions and provided that a quorum is present. For letter ballot votes, a majority is defined as approval by more than half of the qualified voting membership, excluding abstentions.

7.0 OTHER REVIEW¹

Proposals for new American National Standards and proposals to revise, reaffirm, or withdraw approval of existing American National Standards shall be transmitted to ANSI using the BSR-8 form, or its equivalent, for listing in Standards Action in order to provide an opportunity for public comment. If it is the case, then a statement of intent to submit the standard for consideration as an ISO, IEC or ISO/IEC JTC-1 standard shall be included as part of the description of the scope summary that is published in Standards Action. The comment period shall be one of the following:

- A minimum of thirty days if the full text of the revision(s) can be published in Standards Action;
- A minimum of forty-five days if the document is available in an electronic format, deliverable within one day of a request, and the source (e.g., URL or an E-mail address) from which it can be obtained by the public is provided to ANSI for announcement in Standards Action; or
- A minimum of sixty days, if neither of the aforementioned options is applicable.

The secretariat shall determine whether listing of proposed standards actions shall be concurrent with the final committee letter ballot and whether announcement in other suitable media is appropriate.

Views and objections resulting from the above shall be handled in accordance with section 8.0. Any substantive change made in the ANS shall be re-listed in accordance with the following.

8.0 DISPOSITION OF VIEWS AND OBJECTIONS

When the balloting on ANS has been closed, the ballot tally will be forwarded to the chair of the Committee or, if appropriate, of the subgroup; the chair shall determine whether the expressed views and objections shall be considered by correspondence or at a meeting.

Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in Standards Action.

Any comments received in response to the filing of PINS (Project Initiation Notification System) with ANSI for new and revised standards shall be addressed in accordance with clause 2.5 of the most current edition of the ANSI Essential Requirements.

In connection with an objection articulated during a public comment period, or submitted with a vote, an effort to resolve all expressed objections accompanied by comments related to the proposal under consideration shall be made, and each such objector shall be advised in writing (including

¹ Although a 60-day public comment period is not required in all instances, a number of provisions in the ANSI Essential Requirements, when read in combination, satisfy the WTO's 60-day rule. Before adopting a standard, ANSI-Accredited Standards Developers shall allow a period of at least 60 days in total for submission of comments on the draft standard if requested by an interested party within the territory of a Member of the WTO. Exceptions outlined in the rule are permitted due to issues of safety, health or environment. (See WTO Agreement on Technical Barriers to Trade (TBT), Annex 3 Code of Good Practice for the Preparation, Adoption and Application of Standards (CGP) Substantive Provision L.)

electronic communications) of the disposition of the objection and the reasons therefore. If resolution is not achieved, each such objector shall be informed in writing that an appeals process exists. In addition, each objection resulting from public review or submitted by a member of the consensus body, and which is not resolved will be reported to the ANSI BSR. All substantive changes made to an ANS resulting from public comment or in an attempt to resolve a consensus body vote will be re-listed for public review.

HIBCC may consider any comments received subsequent to the closing of the public review and comment period, or shall consider them in the same manner as a new proposal. Timely comments that are not related to the proposal under consideration shall be documented and considered in the same manner as submittal of a new proposal. The submitter of the comments shall be so notified.

Each unresolved objection and attempt at resolution, and any substantive change made in a proposed ANS shall be reported to the consensus body in order to afford all members of the consensus body an opportunity to respond, reaffirm, or change their vote within two weeks.

8.1 REPORT OF FINAL RESULT

The final results of the voting shall be reported, by interest categories, to the Committee.

9.0 SUBMITTAL OF STANDARD

Upon completion of the procedures for voting, disposition of views and objections, and appeals, the proposed standard shall be approved by the HIBCC Board and submitted to ANSI by the secretariat. The proposed ANS will be submitted to ANSI within one year of the close of the public review period, or two years, if an extension is requested in accordance with clause 4.2 of the ANSI Essential Requirements. If the secretariat does not submit the proposal to ANSI within a reasonable period of time, any member(s) of the Committee may make the submittal.

9.1 INFORMATION SUBMITTED

With respect to submitting American National Standards to ANSI without BSR approval, HIBCC shall agree to provide ANSI the following:

1. title and designation of the proposed American National Standard;
2. indication of the type of action requested (that is, approval of a new American National Standard or reaffirmation, revision, or withdrawal of an existing American National Standard);
3. a declaration that applicable procedures were followed;
4. a declaration that the proposed standard is within the scope of the previously registered standards activity;
5. a declaration that conflicts with another American National Standard have been addressed in accordance with these procedures;

6. a roster of the consensus body that indicates: the vote of each member including abstentions and unreturned ballots, if applicable; the interest category of each member; and a summary thereof;
7. a declaration that all appeal actions related to the approval of the proposed standard have been completed;
8. a declaration that the criteria contained in the ANSI patent policy have been met, if applicable; and
9. identification of all unresolved negative views and objections, with names of the objector(s), and a report of attempts toward resolution.

9.2 DISCONTINUANCE OF A STANDARDS PROJECT

An accredited standards developer may abandon the processing of a proposed new or revised American National Standard or portion thereof if it has followed its accredited procedures. A written justification for such an action shall be made available upon receipt of any written request received by the accredited standards developer within 60 days of the date of the final action.

Appeals of such actions shall be made to the HIBCC Board based on procedural noncompliance.

10.0 TERMINATION OF COMMITTEE

A proposal to terminate a Technical Committee may be made by a directly and materially affected interest to the HIBCC Board. Proposals to disband sub-committees should be directed to the primary Committee under which they are governed. The proposal shall be submitted in writing and shall include at least the following:

- Reasons why the Committee (or sub-committee) shall be terminated;
- The name(s) of the organization(s) or committee(s) that will assume responsibility for maintenance of any existing ANS that are the responsibility of the Committee.

In the instance that a sub-committee has governance of an existing ANS, the ANS will revert back to the primary committee under which they were governed.

11.0 COMMUNICATIONS

Copies of correspondence involving issues or decisions (i.e. not routine matters) affecting other sub-committees shall be sent to all affected Committee chairs and the secretariat.

Inquiries relating to Committees should be directed to the secretariat. All replies to inquiries shall be made through the secretariat.

All inquiries requesting interpretation of approved ANS shall be responded to in accordance with HIBCC's interpretation policy. Revisions to the standard resulting from requests for interpretations shall be processed in accordance with these procedures.

12.0 APPEALS

Persons who have direct and materially affected interests and/or who have been or will be adversely affected by a standard within the Committee's jurisdiction shall have the right to appeal procedural actions or inactions of the Committee or the secretariat.

12.1 COMPLAINT

The appellant shall file a written complaint with the secretariat within thirty days after the date of notification of action or at any time with respect to inaction. The complaint shall state the nature of the objections(s) including any adverse effects, the clause(s) of these procedures or the standard that are at issue, actions or inactions that are at issue, and the specific remedial action(s) that would satisfy the appellant's concerns. Previous efforts to resolve the objection(s) and the outcome of each shall be noted.

12.2 RESPONSE

Within thirty days after receipt of the complaint, the Committee chair or secretariat shall respond in writing to the appellant, specifically addressing each allegation or fact in the complaint to the extent of the respondent's knowledge.

12.3 HEARING

If the appellant and the respondent are unable to resolve the written complaint informally in a manner consistent with these procedures, the secretariat shall schedule a hearing with an appeals panel on a date agreeable to all participants, giving at least ten working days notice.

12.4 APPEALS PANEL

The appeals panel shall consist of three individuals plus one alternate who have been elected by the HIBCC Board. In the case that one of the individuals can not take part in the appeals process due to either the inability to attend or if one of the parties in question requests the person be replaced, the alternate shall be used. Panel members shall serve a term of one year. The panel shall consist of a balanced representation from the represented interest groups, and will exclude any persons currently serving within the consensus body.

The appellant has the burden of demonstrating adverse effects, improper actions or inactions, and the efficacy of the requested remedial action. The respondent has the burden of demonstrating that the committee and the secretariat took all actions in compliance with these procedures. Each party may introduce other pertinent arguments, and members of the appeals panel may address questions to individuals. *Robert's Rules of Order* (latest edition) shall apply to questions of parliamentary procedure for the hearing not covered herein.

12.5 DECISION

The appeals panel shall render its decision in writing within thirty days, stating findings of fact and conclusions, with reasons therefore, based on preponderance of the evidence. Consideration may be given to the following positions, among others, in formulating the decision:

- Finding for the appellant, remanding the action to the committee or the secretariat with a specific statement of the issues and facts in regard to which fair and equitable action was not taken;
- Finding for the respondent, with a specific statement of the facts that demonstrate fair and equitable treatment of the appellant and the appellant's objections;
- Finding that new, substantive evidence has been introduced, and remanding the entire action to the Committee or the secretariat for appropriate reconsideration.

13.0 PARLIAMENTARY PROCEDURES

On questions of parliamentary procedure not covered in these procedures, *Robert's Rules of Order* (latest edition) may be used to expedite due process.

ANNEX A: POLICIES

Interpretation Policy

Due to potential liability issues, HIBCC will not provide interpretations of its standards.

All written and oral requests for interpretation of approved HIBCC standards will be received by the HIBCC administrative office. These requests for interpretations will be processed as follows: A form letter shall be sent to the requester, informing the requester that no interpretations are provided and suggests that the requestor participate in HIBCC to revise the standard so it is clearer.

Note: "interpretations of its standards" means the clarification of any portion of the standard(s) that contains ambiguous wording. Explanations of technical specifications are not "interpretations of its standards".

Metric Policy

In general, HIBCC standards will adopt style rules that utilize units of measurement according to the International System of Units (SI), the modernized metric system.

When referencing technical specifications of system components that would potentially use HIBCC standards, the HIBCC standard(s) may adopt the same units of measurement that are used in those technical specifications.

Record Retention Policy

Records relating to any standards activity shall be retained to demonstrate compliance with all aspects of ANSI Essential Requirements and HIBCC's Standard Operating Procedures.

Records concerning new, revised, or reaffirmed American National Standards shall be retained by HIBCC for one complete standards cycle, or until the standard is revised.

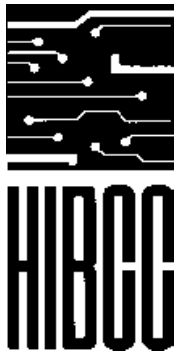
Records concerning withdrawn standards shall be retained for at least five years from the date of withdrawal or for a duration consistent with the audit schedule.

Patent Policy

The Health Industry Business Communications Council (HIBCC), does not hold and does not currently intend holding any essential patent claim(s). HIBCC will comply with the current ANSI Patent Policy.

Commercial Terms & Conditions Policy

The Health Industry Business Communications Council (HIBCC) does not have its own Commercial Terms and Conditions Policy. HIBCC will comply with the ANSI Commercial Terms and Conditions Policy.



Health Industry Business
Communications Council

HIBCC Labeler Identification Code (LIC) Fee Schedule

Required to meet the FDA's UDI Requirements

The first step to meeting the FDA's UDI requirements is to obtain a company prefix from HIBCC. A HIBCC company prefix is called a Labeler Identification Code (LIC), a unique four character alphanumeric code assigned to your organization.

The HIBCC LIC application fee is the only financial transaction you will make with HIBCC in the UDI process. It is a one-time fee, based on you organization's international gross annual sales as reported on your last audited fiscal year. There are no renewal fees or additional fees whatsoever.

The LIC fee schedule is below, as well as on our HIBCC LIC application form. The application form can be [completed online](#) or downloaded as a [PDF](#).

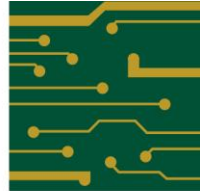
<u>SALES</u>	<u>ONE-TIME FEE</u>	<u>SALES</u>	<u>ONE-TIME FEE</u>
☐ to \$2 million	\$1,000	☐ to \$100 million	\$7,500
☐ to \$5 million	\$1,500	☐ to \$150 million	\$9,000
☐ to \$10 million	\$2,500	☐ to \$500 million	\$12,000
☐ to \$30 million	\$4,000	☐ above \$500 million	\$20,000
☐ to \$60 million	\$5,000		

For any additional questions please contact us at info@hibbc.org or by phone at (602) 381-1091.



Health Industry Business
Communications Council

2525 E. Arizona Biltmore Cir.
Suite 127
Phoenix, AZ 85016
602-381-1091
www.hibcc.org



What is the HIBC Device Identifier?

The HIBC Device Identifier (DI) is the portion of the Unique Device Identifier (UDI) that you are required to submit to the FDA's GUDID. The Production Identifier (PI) is the other portion of the UDI that is not submitted to the GUDID.

The HIBC DI has the following components: the Labeler Identification Code (LIC), the Product/Catalog Code, and the Unit of Measure (also referred to as Package Level Indicator). For more information on Unit of Measure see [HIBCC's Guide to Understanding Unit of Measure](#).

Example:

HIBCC Flag = +
LIC = A999
Product Code = ABC123
Unit of Measure = 0 (single unit)
Check Character = V

DI that is entered in to the GUDID = A999ABC1230

DI that appears on the device label =



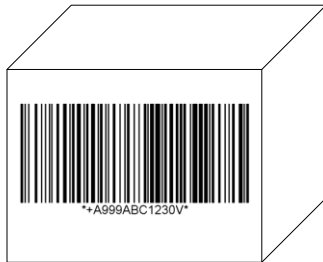
Note: The UDI on the device label includes additional characters (Stop/Start Characters "*", HIBC Flag "+", Check Character, and all other Data Identifiers/Delimiters). Refer to the [HIBC Supplier Labeling Standard](#) for more information.

What do I include in the GUDID?

Primary DI:

The Primary DI is the DI located on the lowest package level that contains a UDI.

Example 1: The package below contains a single device that is exempt from the Direct Marking UDI requirement.



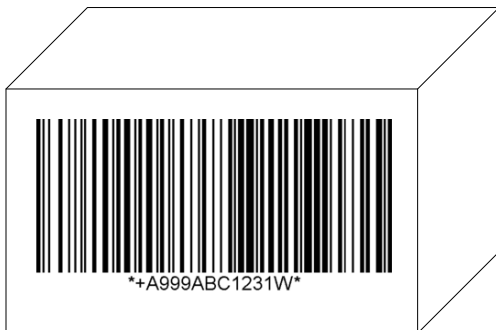
Primary DI = A999ABC1230

Example 2: The device below does not have a package and is Directly Marked with a UDI.



Primary DI = A999ABC1230

Example 3: The package below contains two devices with that are exempt from the Direct Marking UDI requirement (i.e. they are not individually labeled with a UDI).



Primary DI = A999ABC1231

Direct Marking DI:

Devices intended to be used more than once and intended to be reprocessed before each use are required to be directly marked with a UDI.*

The Direct Marking DI component of the UDI can be the same as that which appears on your device label. However, you may choose to use a different DI for direct marking in order to distinguish the unpackaged device from the device packaging. If so, then you must enter *both* the Primary and Direct Marking DIs in the GUDID.

Example: The device below has a Direct Marking DI that is different from the DI on the device packaging. The red arrow points to the DI that is directly marked on the device.



Direct Marking DI: A999DEF4560

Note: The Direct Marking DI must include the LIC, Product/Catalog Code, and Unit of Measure.

*Please review FDA's [UDI: Direct Marking of Devices Draft Guidance](#) for more information.

Unit of Use DI:

A Unit of Use DI is required to be entered in the GUDID when the Primary DI contains more than one device of the same version/model and those devices are not individually labeled with a UDI (see Example 3 under Primary DI).

Example: The package below contains two devices with that are exempt from the Direct Marking UDI requirement (i.e. they are not individually labeled with a UDI).



Primary DI = A999ABC1231

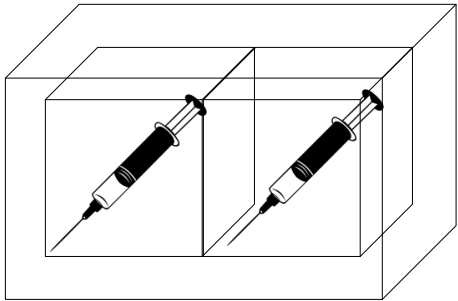
Unit of Use DI= A999ABC1230

Note: The Unit of Use DI does not appear on any of the device labeling.

Package DI:

A Package DI is an identifier for the package configuration that contains multiple units of the base package.

Example: The device below is available in sets of two. The packaging containing both devices is labeled with the Package DI barcode below.



Primary DI = A999ABC1230

Package DI= A999ABC1231

Note: See HIBCC's Guide to Understanding Unit of Measure for more information on package level indicators.

For an explanation of all GUDID fields refer to the [FDA's GUDID Data Elements Reference Table](#).

For additional questions contact HIBCC by email at info@hibcc.org

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2525 E. Arizona Biltmore Circle #127
Phoenix, AZ 85016

(602) 381-1091 • info@hibcc.org





What is Unit of Measure(Package Level Indicator)?

All HIBC UDIs & Auto-ID symbols contain a Unit of Measure field in the Device Identifier (primary data structure). The Unit of Measure is a number (0-9) assigned by the labeler to indicate package level. The Unit of Measure is always located directly after the Product Code. In the image below, the Unit of Measure is the "0" above the red arrow.

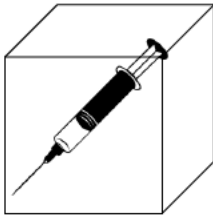


How Do I Assign a Unit of Measure?

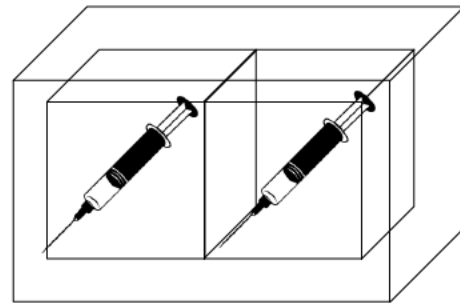
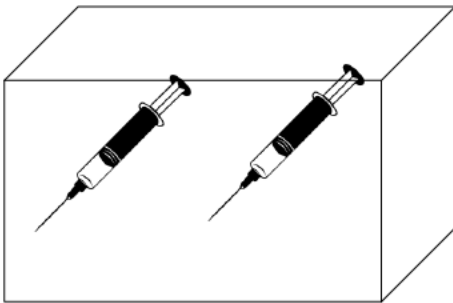
A single unit (i.e. an "each") is always represented by a Unit of Measure of "0". The Unit of Measure "9" is reserved for packages containing variable quantities (i.e. the package quantities are customized). Units of Measure 1-8 are used by the labeler to identify all remaining package levels in ranking order from smallest to largest. The example below shows how to assign the Unit of Measure to different package levels for a device.

Example:

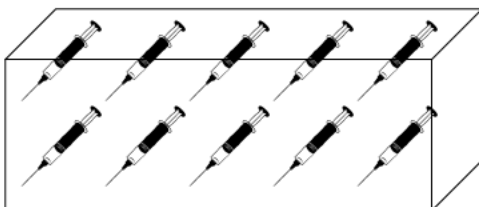
The syringe below is packaged as a single unit, so the Unit of Measure would be "0".



The syringe is also available in sets of two. The images below show two different packaging scenarios for the set of two devices. The Unit of Measure is the same whether the box contains two unpackaged syringes or two individually packaged syringes. The Unit of Measure would be "1" for both scenarios.



Finally, the syringe is available in a case of 10. The Unit of Measure for the case of 10 syringes would be "2". It is also fine to skip numbers and assign a higher Unit of Measure if there is a chance that the device will be available in smaller quantities later on.



Note that the HIBC standard allows labelers to use the same Product/Catalog Number for all package levels of a device (as shown in the example above). The Device Identifier is still unique for each packaging level because the each level is assigned a different Unit of Measure, as required for the FDA's UDI rule.

Note: The term "Package Level Indicator" can be used interchangeably with "Unit of Measure".

For additional questions contact HIBCC by email at info@hibcc.org

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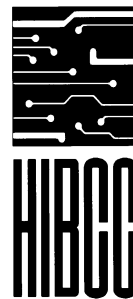


LABELER IDENTIFICATION CODE INFORMATION CHANGE FORM

To make changes to your existing LIC(s) complete this form & return it to our office.

**Health Industry Business
Communications Council**

2525 E. Arizona Biltmore Circle
Suite 127
Phoenix, AZ 85016
Tel: 602.381.1091
Email: info@hibcc.org
Web site: www.hibcc.org



■ LIC Change Form

PURPOSE OF FORM: LABELER IDENTIFICATION CODE (LIC) CHANGES

CURRENT (OLD) INFORMATION:

LIC Number _____

Organization Name

Division / Subsidiary

Name of Official Representative

Title

Phone #

Fax #

Number and Street

City/State/Zip Code/Country

E-Mail Address

By signing below I agree to this change and certify that the above information is correct and true to the best of my knowledge.

Signature of Official Representative

Date

■ LIC Change Form

NEW INFORMATION:

(Please provide official documentation of any organization name changes)

LIC Number _____

Organization Name

Division / Subsidiary

Name of Official Representative

Title

Phone #

Fax #

Number and Street

City/State/Zip Code/Country

E-Mail Address

By signing below I agree to this change and certify that the above information is correct and true to the best of my knowledge.

Signature of Official Representative

Date

■ LIC Change Form

LIC Number _____

LIC CHANGE FEE (in US Dollars): \$50.00

METHOD OF PAYMENT

☐ Please charge to my credit card account. ☐ Visa ☐ MasterCard ☐ AmEx

CREDIT CARD #	EXPIRATION DATE	CSV/CID CODE
---------------	-----------------	--------------

CARDHOLDER'S NAME (as it appears on the card) _____ SIGNATURE _____

CARDHOLDER'S ADDRESS

CARDHOLDER'S CITY STATE ZIP/POSTAL CODE

☐ A check made payable to HIBCC is enclosed.

☐ Please Invoice Me – Purchase Order # _____

Signature of Official Representative	Title
--------------------------------------	-------

Date

Legal Notice: All fees are non-refundable.

FOR OFFICE USE ONLY:

Date Received Form Date Received Payment Date Changes Entered

LABELER IDENTIFICATION APPLICATION

Required for the FDA's Unique Device Identification (UDI) Rule

Included here:

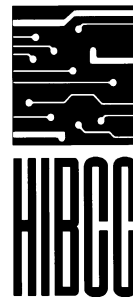
- **Instructions**
- **Form A *LIC Assignment***
- **Form B *Labeler Fee***
- **Form C *Certification Report***

Any organization interested in adopting and using the HIBCC uniform bar coding system must apply for assignment of a Labeler Identification Code (LIC).

To apply for assignment of an LIC follow the steps outlined in the instructions which follow.

**Health Industry Business
Communications Council**

2525 E. Arizona Biltmore Circle
Suite 127
Phoenix, AZ 85016
Tel: 602.381.1091
Email: info@hibcc.org
Web site: www.hibcc.org



■ INSTRUCTIONS: FOR COMPLETING FORM A

(To be completed by all applicants)

Purpose of Application

LABELER IDENTIFICATION CODE (LIC) ASSIGNMENT

1. Contact Information

Enter your organization's name, address and the name, title and telephone number of your organization's official representative to HIBCC. The official representative will represent your organization in all affairs dealing with your code assignment and HIBCC.

Also enter the name, address, title and telephone number of your organization's chief executive officer (CEO). If your organization is a subsidiary or division of a parent organization, you should enter your subsidiary's or division's CEO, not the parent's.

2. Transfer of Assignments

LIC assignments are non-transferable.

■ INSTRUCTIONS: FOR COMPLETING FORM B

(To be completed by all applicants)

Labeler Fee

You must certify your most recent calendar or fiscal year sales level by completing the CERTIFICATION REPORT.

■ INSTRUCTIONS: FOR COMPLETING FORM C

(To be completed by all applicants)

Specify your annual sales and the calendar or fiscal year of those sales. Next, check the appropriate sales category which determines your fee for the LIC assigned. Sign and date and return with your application.

LIC: Enter the fee for the LIC in Section A, Form B (determined in the CERTIFICATION REPORT). Sign, date and send forms A, B, and C to: **HIBCC, 2525 E. Arizona Biltmore Circle, Suite 127, Phoenix, AZ 85016**. Make all checks payable to HIBCC. If paying by credit card send via email to info@HIBCC.org.

FORM A: LIC ASSIGNMENT

PURPOSE OF APPLICATION: LABELER IDENTIFICATION CODE (LIC) ASSIGNMENT

PRIMARY ORGANIZATION:

Primary Organization Name

Division / Subsidiary

Name of Official Representative

Title

Phone

Number and Street

PO Box

City/State/Zip Code/Country

E-Mail Address

Name of Chief Executive Officer

Title

Phone

Address, if different from above

CEO's E-Mail Address, if different from above

	MEDICAL	DENTAL	ANIMAL HEALTH
TYPE OF ORGANIZATION ☐ MANUFACTURER OF GOODS OR SERVICES <i>(check applicable box for primary market)</i> ☐ DISTRIBUTOR/WHOLESALER			

FOR OFFICE USE ONLY:

Date Received Application

Fee

Date Received Payment

LIC #

Date Assigned

Initials

■ FORM B:

LABELER FEE *(complete appropriate section)*

SECTION A: **Labeler Identification Code (LIC) Assignment**

Our organization hereby applies for assignment/registration of a Labeler Identification Code (LIC) from the Health Industry Business Communications Council.

In making such application, we agree to be bound by all rules and regulations of the Council including, but not limited to the Articles of Incorporation, the Bylaws, the Health Industry Bar Code Standard, and any and all other rules and regulations which the Council has now or may hereafter adopt concerning the use of the Health Industry Bar Code Standard and the Labeler Identification Code assigned. The Council will notify us of our assigned Labeler Identification Code upon receipt of our application fee and Council approval of our completed application.

Our organization hereby agrees to indemnify, and hold harmless, the Health Industry Business Communications Council and their officers, directors, employees, agents, successors and assigns from any and all claims, losses, damages, and liabilities whatsoever resulting from the use or misuse of the Health Industry Bar Code Standard and our assigned Labeler Identification Code.

We understand and acknowledge that the Council has taken all reasonable precautions to prevent the assignment of duplicate Labeler Identification Codes. If duplicate codes are assigned, the liability of the Council shall be limited to a refund of the application's Labeler Identification Code fee or the actual damages, if any, whichever is less.

METHOD OF PAYMENT

☐ Please charge \$_____ (amount from above) to my credit card account. ☐ Visa ☐ MasterCard ☐ AmEx

CREDIT CARD NUMBER	EXPIRATION DATE	CSV/CID CODE
--------------------	-----------------	--------------

CARDHOLDER'S NAME (as it appears on the card)	CARDHOLDER'S SIGNATURE
---	------------------------

CARDHOLDER'S ADDRESS

CARDHOLDER'S CITY	STATE	ZIP/POSTAL CODE
-------------------	-------	-----------------

☐ A check in the amount of \$_____ (from above) made payable to HIBCC is enclosed.

☐ Please invoice me directly. Purchase Order Number _____

Signature of Official Representative

Title

Date

■ FORM C: CERTIFICATION REPORT

Please certify your most recent fiscal year sales level. Applicants are required to submit one of the following from the last fiscal/calendar year: Dun & Bradstreet Report, Profit & Loss Statement, or page 1 of your company's Corporate Tax Return (and any related documents). This information will be kept confidential and will only be used to determine the LIC fee.

Gross global sales of all products/devices labeled with your organization's name or brand.

THIS INFORMATION WILL BE TREATED ON A CONFIDENTIAL BASIS
--

Specify annual sales \$_____ for the most recent calendar or fiscal year: _____.

Check the appropriate box and enter the ONE-TIME FEE amount in Section A - LABELER FEE on FORM B.

SALES	ONE-TIME FEE	SALES	ONE-TIME FEE
☐ up to \$2 million	\$1,000	☐ up to \$100 million	\$7,500
☐ up to \$5 million	\$1,500	☐ up to \$150 million	\$9,000
☐ up to \$10 million	\$2,500	☐ up to \$500 million	\$12,000
☐ up to \$30 million	\$4,000	☐ above \$500 million	\$20,000
☐ up to \$60 million	\$5,000		

Legal Notice:

By signing this application you are certifying that all financial information provided is correct and in accordance with the guidelines stated above. If HIBCC determines that the financial information provided is incorrect, you will be invoiced for the balance due prior to issuing your LIC. HIBCC reserves the right to deactivate any LIC that was obtained under false financial pretenses and notify all invested parties. All fees are non-refundable.

Signature of Official Representative

Title

Date

**Health Industry Business
Communications Council**

2525 E. Arizona Biltmore Cir.
Suite 127
Phoenix, AZ 85016
602-381-1091
FAX 602-381-1093
www.hibcc.org



June [REDACTED], 2017

Mr. [REDACTED]
[Company Name]
[Address Line 1]
[Address Line 2]

Dear Mr. [REDACTED]:

We are pleased to welcome your company as a participant in the automatic identification/bar code labeler program. As such your HIBC-compliant labeling will be in compliance with Unique Device Identifier (UDI) requirements, and your participation in standardized product labeling supports the healthcare industry's efforts to improve patient safety and promote effective cost containment practices.

Based on the information provided on your recent application, HIBCC has assigned a Labeler Identification Code (LIC) for your use. The LIC is matched with a permanent record which is maintained in HIBCC's LIC database.

This letter is our official notification of your assignment and should be preserved as your permanent record. Your assigned LIC is as follows:

BD### [COMPANY NAME]

You will use your LIC, in combination with your existing product codes and production information, to create UDIs and bar codes for all your devices.

The integrity of the LIC database depends on your cooperation. Please keep us fully informed of current and accurate information on your LIC by notifying us of any change in your company name or address, as well as any change in your business alignment or ownership, such as a merger, acquisition, dissolution, or creation, elimination or divestiture of divisions/subsidiaries.

The *HIBC Supplier Labeling Standard* is available on our website, www.hibcc.org (copy also enclosed), to assist you in developing your product identifiers. Your close attention to the specifications will enhance the value of standardized automatic identification to the entire industry and assure compliance with UDI and other regulatory initiatives.

I also urge you to consider membership and participation in our organization by becoming an HIBCC Corresponding or Corporate Member (see enclosure). Membership is intended to keep you informed of developments in the use of automatic identification technologies in healthcare.

If we can be of any assistance, please do not hesitate to contact us.

Yours Truly,



President

RAH/cam

Enclosures



Health Industry Business
Communications Council

Agreement of Non-Disclosure of Confidential Information

This LETTER OF AGREEMENT will serve to confirm and set forth the terms of agreement between the Health Industry Business Communications Council (HIBCC) and **NAME** (herein referred to as “Primary Consultant”). In consideration of the mutual undertakings of HIBCC and the Primary Consultant, the parties agree as follows:

In the course of this Agreement, Primary Consultant acknowledges that he may have access to information that HIBCC considers confidential, proprietary and/or sensitive, the disclosure of which could result in substantial and irreparable damage to HIBCC.

Definition of Confidential Information:

Confidential information shall mean business or technical information including, but not limited to, product data, sales data, financial data, customer data, formula processes, techniques and methods or ideas that are not generally known or available. Confidential Information shall also include information of HIBCC Affiliates that HIBCC is under an obligation to maintain in confidence.

No Disclosure of Confidential Information:

Primary Consultant agrees that he will regard and preserve as confidential all Confidential Information of HIBCC and its Affiliates received by Primary Consultant in connection with this agreement. To preserve the confidentiality of such Confidential Information Primary Consultant will not, without first obtaining the written consent of HIBCC, disclose to any person, firm or enterprise, or use for his own benefit, any such Confidential Information.

Limits on Confidential Information:

Confidential Information shall not be considered confidential, proprietary or sensitive only to the extent that such information: (a) is already known to Primary Consultant at the time it is obtained from HIBCC; (b) is or becomes publicly known through no wrongful act of Primary Consultant; or (c) is rightfully received by Primary Consultant from a third party without an accompanying restriction of use or disclosure.

Confidentiality of Work Products:

All work products developed by Primary Consultant for HIBCC and its Affiliates, including but not limited to computer programs and applications and associated documentation, shall be the sole property of HIBCC and are subject to the terms of this Agreement as deemed appropriate by HIBCC.

Terms & Termination:

This Agreement shall remain in effect after termination of the work contract/employment.

This Non-Disclosure Agreement shall be interpreted in accordance with and governed by the laws of the State of Arizona.

In the event of breach or a threatened breach of terms and conditions of this Agreement, HIBCC shall be entitled to immediate injunctive relief to prevent the use or disclosure of Confidential Information, in addition to all other remedies available to it at law or equity.

Any suit or action arising out of a dispute under this Agreement shall be brought only in a court of competent jurisdiction, state or federal, sitting in Phoenix, Arizona. Both parties agree to accept venue in such county.

Accepted this 8th day of October, 2013.

HIBCC

By _____



Title: President & CEO

Primary Consultant

By _____

Name:

Title: Consultant

Health Industry Business Communications Council

**Registered Labelers:
Accredited Auto-ID Labeling Standards**



The following companies (and/or their subsidiaries/divisions) have applied for a Labeler Identification Code (LIC) assignment with HIBCC or one of our international affiliates. By doing so, they have demonstrated their commitment to patient safety and logistical efficiency for their customers, the industry and the public at large.

Any organization that is interested in using the HIBC uniform labeling system may apply for the assignment of one or more LICs.

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For more information, please contact the HIBCC office at:

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info@hibcc.org
www.hibcc.org

Austria

AMI GmbH
Bender Medsystems GmbH
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Australia

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Apollo Medical Imaging Technology Pty Ltd
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Kico Knee Innovation Company Pty Ltd.
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Bio-Rad RSL
Bio-Rad Lab Inc Clinical Diag. Group
Biosource Europe SA
Cilag NV
Coris Bioconcept
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icomatrix NV
Int'l Pharmaceutical Services BVBA
Johnson & Johnson International
Medical Products
Materialise NV
Mayne Pharma
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Molnlycke Europe SA
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Pierre Fabre Benelux
Scimed Europe S.P.R.L.
Théa Pharma SA

Brazil

Angelus Indústria de Produtos Odontológicos S/A
Biolab Diagnostica SA
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Dentsply Ind E Com Ltda Brazil
Johnson & Johnson Prod. Prof. LTDA
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British Virgin Islands

Registered Labelers

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Sybron Dental Specialties

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CardioMed Supplies

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Clearwater Clinical Limited

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Delfi Medical Innovations

DenPlus Inc.

Dental Savings Club

Dental Wings Inc.

Diagnos Inc.

Diagnostics Biochem Canada Inc.

Dymedso Inc.

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Etymonic Design Incorporated

Fio Corporation

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Glustitch, Inc.

GS Medical Packaging Inc.

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ID Labs, Inc.

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Johnson & Johnson Med. Prod.

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Octostop

Oculo-Plastik, Inc.

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China (includes Hong Kong)

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 Evolutis SAS
 FFDM Pneumat
 Fluoptics
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 Hexacath Sarl
 IMACTIS SAS
 Implants Serv. Orthopediques (Iso-Ortho)
 Intervascular Sas
 Ioltech Laboratoires
 Itena-Clinical
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 Lisi Medical Orthopaedics
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 Medicoscop
 Medicea
 Med-Imaps
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 Micro-Mega SA
 Neosteo
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 Phakos
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Virtual Ports, Ltd.

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Adler Ortho S.p.A.

ASA Dental SPA

B & B Dental Srl

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Biotech S.R.L.

Biotech SRL

Biotechne SRL

Blue X Imaging SRL

BMI Biomedical International SRL

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Critikon-Johnson & Johnson Prof. Prod.

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De Götzen S.rl.

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IGEA SRL

Intrauma SRL

Johnson & Johnson Medical Holding SPA

Kerr Italia SPA

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Next Sight SRL

NGC Medical SPA

Nidek Technologies Srl

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Optikon 2000 SPA

Paramed S.R.L.

Q.R Srl

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RS Medica SRL

Sclavo Diagnostics International SRL

Sentinel CH. SPA

Sintea Biotech SPA

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Cavex Holland BV	Guerbet Nederland BV	MSD
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Central Lab VD Bloedtransfusiedienst	Hexal BV	N.V.I
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Christiaens BV	Homeuropa BV	New Neopharm BV
Clinimed Holding BV	ICI-Farma	Nikinc Dental B.V.
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Eli Lilly Nederland BV	Kring-Apotheek BV	Warner Lambert
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EU-Pharma BV	LAGAP BNL BV	Pfizer BV
Eureco-Pharma BV	Leids Universitair Medisch Centrum	Pharbil
Eurobase BV	Leo Pharma BV	Pharbita BV
Eurocept Pharmaceuticals	Leyden Delta BV	Phardis BV
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Registered Labelers

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Sanofi Aventis
 Sanofi Aventis Nederland BV
 Sanofi Winthrop,
 Bristol Myers Squibb VOF
Sanquin
Schering-Plough Nederland BV
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Sigma Tau Ethifarma BV
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Spruyt Hillen BV
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Stephar BV
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Stichting Registratie Beheer (SANDOZ)
Stichting Ziekenhuis Leyenburg
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Technomed Europe BV
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Terapharm BV
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Viatris Manufacturing BV

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Wellcome Pharmaceuticals BV
Wyeth Laboratoria BV
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Zambon Nederland BV
Zyma-Nederland BV

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Nycomed Imaging AS
Saga Dental Supply AS

New Zealand

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Philippines

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Johnson & Johnson Medical Prof. Prod.
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U&I Corporation

Spain

Howmedica Faimon SA
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Johnson & Johnson Prod. Prof.
Metalor Iberica
Transcendencias Comerciales SL.

Sweden

AB Ardent
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Hospal - Gambro Renal Products
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Medscand Medical AB
Molnlycke Health Care AB
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Coltène AG
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 Tempir
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 Medical & Industrial Equipment
 DePuy International, Ltd.
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 Grant Instruments (Cambridge), Ltd.
 HeartSine Technologies Ltd.
 Howmedica (Uk) Limited
 Hyaltech, Ltd.
 Iolab Intraocular
 IVAX Pharmaceuticals UK
 J & J Medical Ltd. UK
 J & J Ortho Clinical Diag - Wales
 Johnson & Johnson Orthopaedics Ltd
 Johnson & Johnson Prod.Prof. Ltda.
 Lidco, Ltd.
 Lloyds TSB Registrars / BOC Health Care
 Medtrade Products Limited
 Metalor Dental Products, Ltd.
 Mirada Medical Ltd.
 Mitsubishi Pharma Europe, Ltd.
 Myconostica, Ltd.
 Neoligaments, Ltd.
 Orthodynamics
 Ortho-Trauma International LLP
 Paxman Coolers Ltd.
 Perspectum Diagnostics Ltd.
 Planar PLC
 Plasma Surgical Investments
 Plasma Surgical, Ltd.
 Portex, Ltd.
 Poulten & Graf, Ltd.
 Ranbaxy UK, Ltd.
 Ranier Technology Ltd.
 Real Doctors
 Regent Hospital Products, Ltd.
 LRC Products, Ltd.
 ScanTrack Healthcare Systems, Ltd.
 Sherwood Medical Int.
 Smith & Nephew Healthcare, Ltd.
 Smiths Industries
 Stanmore Implants Worldwide, Ltd.
 SIW Holdings, Ltd.
 Stryker Howmedica Osteonics
 Sulzer Vascutek, Ltd.
 Summit Medical, Ltd.
 Surgicraft (Mandaco 569) Ltd.
 Synthes
 Technical & General Ltd.
 Tensonix Limited
 The Dental Directory,
 Billericay Dental Sup. Co.

Thermo Fisher Scientific
 Tissue Science Laboratories PLC
 Vadin Implants, Ltd.
 Vicor Motion Systems Ltd. (A Wholly
 Owned Subsidiary of OMG PLC)
 Vision RT

United States

3M
 3M Imaging
 3M Med\Surg
 3M Orthopedic
 3M Pharm
 3M Vision Care
 4M Screening Solutions, Inc.
 410 Medical Innovation LLC
 A & A Medical Supplies, Inc.
 AADCO Medical Inc.
 A Plus International
 A.R. Hinkel Co., Inc.
 Aalto Scientific, Ltd.
 Audit Microcontrols, Inc.
 Aaron Medical Industries, Inc.
 Bovie Medical
 Omniflex
 Aastrom Biosciences
 Abbott Laboratories
 Abbott Critical Care
 Abbott Diagnostic
 Abbott Hospital Production
 Abbott Pharma. Production
 Perclose, Inc.
 Abco Dealers, Inc.
 Ability One Corporation
 Absorbent Products Company, Inc.
 Access Closure, Inc.
 Acclarent, Inc.
 Accuray Inc.
 Accuvein, LLC
 ACell, Inc.
 Acme United Corporation
 ACMI
 Acorn Engineering Company
 Whitehall Manufacturing
 Acumed, Inc.
 Acutus Medical
 AdDent, Inc.
 Addition Technology, Inc.
 A-Dec, Inc.
 Adenna Inc.
 Adhezion Biomedical, LLC

Registered Labelers

Adler Instrument Company	Alevio, LLC	Anchor Innovation Medical, Inc.
Adroit Medical Systems	AliveCor	Anesthesia Associates, Inc.
Ad-Tech Medical Instrument Corporation	All American Dental Supply LLC	Anesthesia Medical Specialties, Inc.
Advan Dx, Inc.	All Dental Prodx, LLC	Angeion Corporation
Advance Medical Designs, Inc.	Allergan, Inc.	Angiodynamics
Advanced Back Technologies, Inc.	Alliance Spine, LLC	E-Z-EM, Inc.
Advanced Biomaterial Systems	Alliant Enterprises, LLC	Angioguard, Inc.
Advanced Bionics LLC	Alliant Healthcare Products	Angioscore Inc.
Advanced Breath Diagnostics, LLC dba Cairn Diagnostics	Allo Source	Angiotech
Advanced Circulatory Systems, Inc.	Almore International, Inc.	Angiotech Biocoatings Corp.
Advanced Instrumentation for Medicine, Inc.	ALPCO	Angiotech Pharmaceuticals, Inc.
Clear Flush	Alpha Medical Instruments, LLC	Anika Therapeutics, Inc.
Advanced Instrumentations, Inc.	Alpha-Tec Systems, Inc.	Anmuth Medical International
Advanced Maternity Innovations	Alto Development Corporation	Ansell Healthcare Products LLC
Advanced Medical Optics	A & E Medical Corporation	APC Workforce Solutions, LLC dba Zero- Chaos
Advanced Meditech International, Inc.	Altracore Biomedical	APDM
Advanced Orthopaedic Solutions, Inc.	AltroCare Inc.	Apdyne Medical Company, Inc
Advanced Vertebral Solutions, LLC	Altus Spine	Apex Biologix
Advanced Vision Science	AMCOL International	Apogent Technologies
Advantec Vascular Corporation	Chemdal Corporation	Erie Scientific Co.
Advin Biotech	Amedica/US Spine	Nalge Nunc Co.
Aesculap Instruments Corp.	American Australian Medical	Nerl Diagnostics Corp.
Aesthetic & Reconstructive Technologies	American Cyanamid	Richard Allan Scientific
AFP Imaging Corporation	Davis & Geck	Apotheus Laboratories, Ltd.
Dent-X Corporation	American Dental Cooperative	Scott Laboratories, Ltd.
AFP Manufacturing, Inc.	American Dental Implant Corp	Applied Medical Resources
AGA Medical Corporation	American Dental Supply, Inc.	Applied Spine Technologies
Agent Medical, LLC	American Diamond Instruments	Aptis Medical, LLC
AGFA Corporation	American Health Products Corp.	Aqueduct Critical Care, Inc.
Matrix Division	Quinton Instrument Company	Arch Therapeutics
AGFA Healthcare	American Health Service Sales Corp	Arcos, Inc.
AIDI Biomedical	American Home Products Corp.	ArcScan Inc.
AirStrip Operations, LLC	Argyle Division of Sherwood	Ardent, Inc.
Air Techniques, Inc.	Dover Urologicals Div.	Argon Medical Devices, Inc.
All Pro Imaging	Monoject Div. of Sherwood Medical	Armour Pharmaceutical Company
Airsep Corporation	Oxford Chemistries Div.	USV Lab. Div. Pharma Corp.
Aktina Medical Corp.	Oxford Lab Supplies Div.	ARP Manufacturing, LLC
Alafair Biosciences	Oxford Liquid Handling Div.	Arquilla, Inc. dba X-Cel X-Ray Corpora- tion
Alba -Waldensian, Inc.	Sherwood, Davis & Geck	Arrhythmia Solutions Inc
Alba-Waldensian Health Prod. Div.	US Clinical Products	Arrow International, Inc.
ALC Enterprises Inc	Veterinary Div. of Sherwood	Precision Products
Aura Medical LLC	Wyeth-Ayerst Laboratories	Arstasis, Inc.
Alcide Corporation	American I.V. Products	Arteriocyte, Inc.
Alcon Laboratories	American Sterilizer Company	Arteriocyte Medical Systems, Inc.
Pharmaceuticals	American Tooth Industries	Arterys Inc
Alycone Lifesciences Inc.	Amerisource Bergen	Arthrex, Inc.
Alere San Diego Inc dba Biosite, Inc.	Amersham Health/GE	Arthrosurface, Inc.
	Amerx Health Care Corp.	Arthrotek
	Amici, Inc.	
	Amsino International, Inc.	
	Anatomical Concepts, Inc.	

Registered Labelers

ArtVentive Medical Group	B G Industries, Inc.	Bemis Health Care, Inc.
ArtVentive	Bacchus Vascular	Bemis Mfg. Co.
Aseptica, Inc.	Bacharach, Inc.	Benco Dental Supply Co.
Aspen Surgical Products, Inc.	Bacterin International, Inc.	Benson Medical Instruments Co.
Aspyra, LLC	Bahadir USA LLC	Bergan Mercy, Inc.
Astra USA	Banta Healthcare	Berkley Medical Resources, Inc.
Astron Dental Corporation	Bard Peripheral Vascular	Berns Medical LLC
Astute Medical, Inc.	Barnstead International	Best Vascular Inc.
Asuragen, Inc.	Baron Medical Corp.	BETA Biomed Services, Inc.
Athena Champion	Barriermed, Inc.	Better Water LLC
Athena GTX	Barriermed Glove Co.	Biddle & Crowther Company
AtheroMed, Inc.	Barrx Medical, Inc.	Bihani Corporation dba American Medicals
Ati Orion	Basic Dental Implant Systems, Inc.	BiO2 Medical, Inc.
Atlas Spine, Inc.	Bausch & Lomb, Inc.	Bio2 Technologies, Inc.
ATOMO Dental, Inc.	Baxa Corporation	Bio Compression Systems
Atricure, Inc.	Baxter Healthcare Corp.	Bio Derm, Inc.
Atritech, Inc.	Baxter Compass	Bio Medical Enterprises, Inc.
Atrium Medical Corp.	Bay Corporation	Bio Merieux, Inc.
ATS Medical, Inc.	Bayer Corporation	Bio Plas, Inc.
Auric Enterprises, Inc.	AGFA Division	Bio Sb Inc
Diack	Bayer Healthcare	Bioaccess, Inc.
Aurora Manufacturing LLC	Diagnostics	Biocompatibles, Inc.
Auris Health Inc	Beacon Endoscopic	Biocompatibles International PLC
Aurora Spine, Inc.	Bear Down Consulting dba Pure	Biocompatibles Cardiovascular, Inc.
Aus Systems Pty Ltd	Enrichment	Bioflo LLC
Austenal Dental, Inc.	Beaverstate Dental Inc	BioLife Solutions, Inc.
Authentic Options, LLC	Beckman Coulter, Inc.	Biological & Environmental Control Labs
Automated Medical Products Corp.	Australia	Biomed Diagnostics, Inc.
Autonomic Technologies	Kentucky	Biomed Packaging Systems, Inc.
Avantis Medical Systems, Inc.	Primary Care Diagnostics	Bio-Medical Devices, Inc.
Avanti Systems, Inc.	Becton, Dickinson & Company	Biomerieux, Inc.
Aveco Health LLC	Acutecare	Biomerix Corporation
Aventusoft, LLC	Becton Dickinson Division	Bion Enterprises Ltd. dba MBL Bion
Avenu Medical Inc.	Diagnostic Instrument Systems	Bioness, Inc.
Avid Medical, Inc.	Immunocytometry Systems	Bionica Inc.
Avinger, Inc.	Infusion Systems	BionX Medical Technologies
Awareness Technology Inc.	Labware	Bioplate, Inc.
Axiobionics	Medical Glove Division	Biopro
Axiom Medical, Inc.	Medical Technique Products	Bio-Rad Laboratories, Inc.
Axis Dental Corporation	Microbiology Systems	Bio-Rad Lab Inc Clinical Diag. Group
Axis Orthopaedics Corp	Phase Medical, Inc.	Redmond Operations
Axo Gen, Inc.	Pharmaceutical Systems	Biosculpture Technology, Inc.
Axonics Modulation Technologies, Inc.	Vacutainer Systems	Bioseal Medical Packaging Concepts
B & B Dental Ceramic Art, Inc. dba 3D	Vascular Access	Biosearch Medical Products, Inc.
BioCAD	Beiersdorf, Inc.	Biosensics LLC
B Braun Medical, Inc.	Beiersdorf Medical	Biosphere Medical, Inc.
B Braun Interventional Systems	Jobst Institute, Inc.	Biosynergy, Inc.
Burrn Mfg. Division	Beitler McKee Optical Company	Biotech, Inc.
	Bel-Art Products	
	Maddak, Inc.	
	Belle de St. Claire	
	Bellegrove Medical Supply, Inc.	
	Belport Company	
	Gingi-Pak	

Registered Labelers

Biotek Instruments, Inc.	C R Bard, Inc.	Cardio Medical Solutions, Inc.
BioTex, Inc.	Bard Access Systems	Catheter Connections, Inc.
BioTime, Inc.	Bard Canada, Inc.	Cayenne Medical, Inc.
Biotricity	Bard Cardiopulmonary	CC Wellness LLC
Biotrol International	Bard Critical Care Div.	Cederroth, Inc.
Pro-Dex, Inc.	Bard Electrophysiology	Celera Corporation
Bioventus LLC	Bard Interventional Products	Celerus Diagnostics
BioVue, LLC	Bard Medical	Cellay, LLC
Birchwood Laboratories, Inc.	Bard Medsystems Division	Cellera, LLC
Bisco, Inc.	Bard Radiology Division	Cenogenics Corporation
Black & Black Surgical, Inc.	Bard Reproductive Systems	Centrix, Inc.
Blackstone Medical, Inc.	Bard Urological Division	Century Plastics
Block Medical, Inc.	Bard Vascular Systems Division	Mac-Lee Medical Products
Blue Endo	Birtcher Medical	Cerapedics, Inc.
BodyTrace, Inc.	Davol Inc/Bard Access	Certol International, LLC
Boehringer Laboratories, Inc.	Medchem Products, Inc.	Cervilenz Inc.
Boekel Industries, Inc.	USCI Division	Cetylite Industries, Inc.
Bone Foam Inc	Cabot Medical Corp.	CFS Dental Inc.
Bone Solutions LLC	Cactus LLC	Chameleon Dental Products Inc.
Boots-Celltech Diagnostics Ltd.	Caire, Inc.	Channel Investments, LLC dba Tria Beauty
Boston Endo-Surgical Technologies, Inc.	Calhoun Vision, Inc.	Chart Inc.
Boston Scientific Corporation	Calvary Spine, LLC	Chatsworth Latex, Inc.
Advanced Bionics	Camber Medical Technologies	Checkpoint Surgical, Inc.
Cardiac Assist	Camber Spine Technologies, LLC	Chesebrough-Ponds, Inc.
EPT	Cambridge Heart, Inc.	Home Services Division
Interventional Technologies, Inc.	Cameron Miller Inc.	Chester Labs, Inc.
Meadox Medicals, Inc.	Candelis, Inc.	Chestnut Medical
Medi-Tech	Captiva Spine	Children's Hospital Medical Center
Microvase Endoscopy	Capture Vascular, Inc.	Christie Medical Holdings, Inc.
Microvase Urology	Carbon Medical Technologies	Churchill Medical System, Inc.
Scimed	Cardiac Designs, Inc.	Cianna Medical Inc.
Target Therapeutics	Cardiac Science Corporation	Cida
Bound Tree Medical	CardiacAssist, Inc.	Cincinnati Surgical Company
Braemar Manufacturing LLC	Cardica, Inc.	CIRCA Scientific, LLC
Brain Sentinel, Inc.	Cardinal Health	Circadiance, LLC
Branchpoint Technologies, Inc.	Alaris Medical Systems	Circon Corporation
Brennen Medical, Inc.	Cardinal Scale Mfg. Co.	Cabot Medical Corporation
Breveon, Inc.	Detecto Scale	Citra Anticoagulants, Inc.
Bridger Biomed, Inc.	Cardiogenesis Corp.	Civco Medical Solutions
Briggs Medical Service Corp.	Cardiomems, Inc.	Clarus Medical, LLC
Brinkmann Instruments Co., Inc.	Cardionics	ClarVista Medical
Bryan Medical Inc	Cardiovascular Dynamics, Inc.	ClearCorrect, Operating
BSD Medical Corporation	Interpoint Medical Systems	ClearCorrect, LLC
Buckeye Medical Technologies Ltd.	Cardiovascular Innovations, LLC	ClearFlow, Inc.
Bulbtronics Inc.	Cardiva Medical, Inc.	Clear Guide Medical LLC
Burke/Leisure Lift Inc.	Carelife USA	Clearnmedical
Burke L Mays and Associates, Inc.	Careside Medical	ClearPath Surgical, Inc.
Burton Medical	Carestream Health, Inc.	
Busse Hospital Disposables	Cargus International	
CCRI, Inc.	Carl Parker Associates, Inc.	
	Dental Materials Group	
	Mydent Corporation	
	Castle Professional Services, Inc.	

Registered Labelers

ClearSpec LLC	Cooley & Cooley, Ltd.	Cygnus, Inc.
Clearwater Colon Hydrotherapy, Inc.	Cooper Biomedical, Inc.	Cypress Medical Products, LP
Cleveland Medical Devices, Inc.	Coors Ceramics Company	Cytogen Corporation
Clinical Innovations, Inc.	CoorsTek Medical	CytoSorbents, Inc.
Clinical Instruments International, Inc.	Corbin Clinical Resources, LLC	D&S Dental
CliniComp International Inc.	CoreLink	Daavlin Distributing Company
Clinimed, Inc.	Corning, Inc.	Dade International
Clinipad Corp.	Corpak MedsySystems, Inc.	Dade Chemistry Systems, Inc.
CME America, LLC	Correx, Inc.	Dale Medical Products, Inc.
CMP Industries LLC	Cosmedent, Inc.	Dallen Medical, Inc.
Coalescent Surgical, Inc.	Cottrell, Ltd.	Darby Dental Supply, LLC
Coapt, LLC	Advance Suture, Inc.	DARCO International Corporation
Coaxia, Inc.	Alliance Western Mfg.	Data Innovations LLC
Codonics, Inc.	Prochem Company	Data Medical
Coeur, Inc.	CP Medical, Inc.	Datascope Corporation
Coeur Medical	Theragenics	David Scott Company
Cohera Medical, Inc.	CPAC	Davryan Laboratories, Inc.
Coherex Medical	Allied Diagnostic Imaging Resources	Daxor Corp
Collagen Matrix, Inc.	Cranial Technologies	D.B.I. America Corporation
Coloplast, Inc.	Crest Electronics	DCI International
Coloplast AS	DBA Crest Healthcare Supply	Decon Laboratories
Coltene/Whaledent, Inc.	Cretex	Delcath Systems, Inc.
Columbia Diagnostics, Inc.	RMS Company	Delta Gloves
Combat Medical Systems, LLC	Critical Diagnostics	Delta Hi-Tech Inc.
Comfortex, Inc.	Criticare, Inc.	Delta Surgical Instruments, Inc.
Avatar Enterprises	Infusion Devices	Deltec
Compass International Innovation, Inc.	Criticare Technologies Inc.	Graseby Medical, Inc.
Compression Therapy Concepts	CrossBay Medical, Inc.	Denali Corporation
Computer Sports Medicine, Inc.	Crosstex International	Den-Mat Holdings, LLC
Con Med	Crosstrees Medical, Inc.	DeNovo Products, LLC
Conceptus, Inc.	Cryovascular Systems, Inc.	Dentalree.com International Inc
Conforma Laboratories, Inc.	CSC Scientific Co., Inc.	Dental Health Products, Inc.
Conformis, Inc.	CS Medical LLC	Dental Technologies, Inc.
Conmed Corp.	Cuattro Medical, LLC	Den-Tal-Ez, Inc.
Andover Medical	Cura Medica LLC	Custom Vacuum
Aspen Laboratories, Inc.	Curaseal	Den-Tal-Ez Equipment
Linvatec	Cure Medical LLC	Star Dental
Conor Medsystems	Curiteva LLC	Denticator International, Inc.
Consolidated Polymer Tech., Inc.	Currie Medical Specialties	Dentium USA
Consolidated Research of Richmond, Inc.	Curtin Matheson Scientific, Inc.	Dentsply International, Inc.
Constant Care Technology, LLC	Custom Spine, Inc.	Ash USA
Contec, Inc.	Custom Ultrasonics, Inc	Ceramco, Inc.
Control Company	Customer Service Associates, LLC	Dentsply Caulk De Mexico SA
Control Medical Technology	CSA Service	Dentsply GAC International
ControlRad, Inc	Cuyahoga Falls General Hospital	Dentsply GmbH
Cook Group, Inc.	CVR Global, Inc.	Dentsply Industria E Comeri
Cook Biotech, Inc.	Cx Orthodontic Supply, LLC	Dentsply, Ltd.
Cook Urological	Cyber Medical Imaging dba XDR	Dentsply Raintree Essix
Wilson-Cook Medical, Inc.	Radiology	Dentsply Tulsa Dental Specialties
		Professional
		Prosthetics Division
		Ransom & Randolph Co.

Registered Labelers

Sultan Healthcare The L D Caulk Co.	Doctors Regional Medical System	Eminent Extremities LLC
Dent Zar Inc.	Doctors Research Group, Inc.	Eminent Spine, LLC.
DEP Shape Memory Therapeutics, Inc.	Domino Pads LLC	Encore Medical LP Encore Soft Goods
DePuy, Inc.	MeLuna USA	Endius, Inc.
DePuy Ace Medical	Dow Corning Corp.	Endocardial Solutions, Inc.
Derby Dental Laboratories	Dragon Heart Medical, Inc.	EndOclear, LLC
Deroyal Industries, Inc.	Drummond Scientific Company	Endoco, Inc. dba Ultimate Dental
Deroyal Technologies, Inc.	DT MedTech, LLC	Endodent, Inc.
Devax, Inc.	Duchesnay USA, Inc.	Endologix, Inc.
Devicor Medical Products, Inc.	Dukal Corporation	Endoscopic Technologies, Inc. dba Estech
Dexide, Inc.	Duplex Products, Inc.	Endothelix
Iotec Industries	Dura Tap LLC	EndoVantage LLC
Nurse Assist	DUSA Pharmaceuticals, Inc.	Endure Industries
Trotec Medical Corporation	Dux Dental	Engage UNI, LLC
Dey Laboratories LP	DxNA LLC	Engineered Medical Systems
DGIMED Ortho, Inc.	Dymicron	Engineered Tissue Solutions (ETS)
DHD Healthcare	Dynarex Corporation	Enhancement Medical, LLC
Diacor Inc.	Dynatech Laboratories, Inc.	Enlightenvue, Inc.
Diagnostics for the Real World Ltd	E Dental Products	Enochs Manufacturing, Inc.
Diamatrix, Ltd.	E I Dupont de Nemours	Enpath Medical, Inc.
Int'l. Science & Technology, LP	Dupont Critical Care-Med Prod. Dept.	Lead Technologies Div.
Diamond Orthopedic LLC	Medical Products Department	ENT Innovations
DIamoDent	Eastern Systems Research, Inc.	Cytophil, Inc.
Diasol, Inc.	ESR Medical Products Group	Entellus Medical
Diasorin, Inc.	Eastman Kodak Company	Enterprise Systems, Inc.
Diasorin SPA	Eclipse Medical, Inc.	Entopsis LLC
Dicom Grid dba Ambra Health	Eco Lab	Entrotech Life Sciences Inc.
Di-Chem Inc	Edge Biologicals Inc	Enzyme Industries, Inc.
Difco Laboratories, Inc.	Edge Endo, LLC	EpiEP, Inc.
Digital Cognition Technologies	EEG Software LLC	Epimed International, Inc.
Digital Heat Corporation	EFOS, Inc.	EPIX Orthopaedics Inc.
Dipro Diagnostic Products	Eisertech	Epsimed LLC
Dirac Formulation Medical Science Co., Ltd.	Ekso Bionics, Inc.	Equipmed USA LLC
DirectCrown Products	Ekos Corporation	Erie Scientific International
Disc Motion Technologies	EKR Therapeutics, Inc.	Barnstead International
Disorb Systems, Inc	Electromed, Inc.	ESI, Inc.
DistribuDent LLC	Electromedical Technologies, LLC	Essential Dental Systems, Inc.
Dittmar, Inc.	Electromedics, Inc.	Essential Medical, Inc.
Diversatek Healthcare	Electronic Development Labs, Inc.	Ethicon Inc. and Ethicon Endo
Dixtal Medical, Inc.	Eli Lilly & Company	Ethox Corporation
Dixtal Biomedica Indus. e Comercio, Ltd.	Dista Products	EUSA Global LLC
DJ Orthopedics, LLC	E.M. Adams Company, Inc.	ev3 Inc.
DMG America LLC	Embla Systems	E-Vac, Inc.
Goldsmith & Revere	Embolx, Inc.	eVent Medical Ltd.
DMX-Works Imaging, Inc.	EMD Chemicals, Inc.	Evergreen Orthopedic Research Lab LLC
DNTLworks Equipment Corporation	Emerald Supply	dba Operativ
DOC Development, Inc.	Emerge Diagnostics Inc.	Evergreen Scientific, Inc.
Doctor Down, Inc.	Emergency Medical Education Tech Sys.	

Registered Labelers

Evolution Spine, LLC	Fujifilm	G-F Health Products, Inc.
Evoqua Water Technologies, LLC	Fujifilm Electronic Materials USA, Inc.	GFC Bridgeview, Inc.
Exactech Inc.	Fujisawa USA, Inc.	Derma Care Div.
Exami-Gowns, Inc.	Fuller Laboratories	Ghost Mfg. LLC
ExoToe LLC	Fusion Dental Implants LLC	GI Dynamics Inc.
Express Diagnostics International, Inc.	Fusion Medical Technologies, Inc.	Gibbons Surgical Corporation
Exsomed Corporation	Fusion Orthopedics, LLC	Gillette
Extremity Medical LLC	Future Health Concepts, Inc.	Oral-B Laboratories
Eyekon Medical, Inc.	Galileo Corporation	Gimbel Glove Company, LLC
Eyenez LLC	Leisegang Medical, Inc.	Gimbel Medical Glove Company, LLC
E-Z-EM, Inc.	Galt Medical Corp.	Glasir Medical, LP
EZ Medical Supply LLP	Theragenics	GlasSpan
FareTec, Inc.	Gambro Co.	Glaukos Corporation
Fenem, Inc.	Gamma Biologicals, Inc.	Global Biomedical Technologies, LLC
FFM Med Reps, LLC	Division of Imucore	Global Dental Science LLC
Excel Medical Products, LLC	Gammex Inc.	Global Diabetic Distributors Inc.
FiberOptic Bulbs, Inc.	Garreco, LLC	Global Health Solutions
Fiberoptic Components, LLC	Gateway Medical, Inc.	Global Manufacturing Industries, LLC
Fibralign Corp.	Gaymar Industries, Inc.	GlobalMedia Group, LLC dba GlobalMed
Fidia Pharma USA Inc.	Medisearch PR, Inc.	Global Medical Products, Inc.
Fine Surgical Instruments, Inc.	Gaymar Industries, Inc.	dba Tava Surgical Instruments
Fisher Healthcare/Curtin Matheson Scient.	GC Corporation	GlobalMed Technologies
Pacific Hemostasis	GC America, Inc.	Globe Enterprises, Inc.
Fisher Scientific	GC Orthodontics America	Gobiquity, Inc.
Chemical Mfg. Division	GE Healthcare	Golden Brothers, Inc.
Diagnostics Division	Geisinger Foundation	Gold Standard Diagnostics
Instrument Mfg. Division	Geisinger System Services	Gold Standard Orthopaedics, LLC
Five Star Orthodontic Lab & Supply	Gelman Sciences, Inc.	Good-Lite Co.
Fixes 4 Kids, Inc.	Gendex Corporation	Good Samaritan Hospital
FKS Health and Life Medical Care Inc	Gendex Dental X-Ray	Legacy Health System
Flashback Technologies Inc	Gendex Europe	Goosen Enterprises, Inc.
Florida Medical Industries, Inc.	Midwest Dental Products	GRA Medica
FloSpine, LLC.	Universal X-Ray	Graham-Field
Flow-FX, LLC	General Glassblowing Co., Inc.	Everest and Jennings
Flowmedica, Inc.	Generic Medical Devices	Gramercy Extremity Orthopedics
Forbes Rehab Services, Inc.	Genesee BioMedical, Inc.	Grande Ronde Hospital
Forestadent USA, INC	Genesys Spine	Graphic Controls Corporation
Forest Medical, LLC	Genetic Laboratories Wound Care, Inc.	Great Basin Scientific
Foxhollow Technologies, Inc.	Derma Services	Great Lakes Orthodontics, Ltd.
FreeHold Surgical, Inc.	Genetics Systems Corp.	Greenville Hospital System
Fresca Medical, Inc.	Genii, Inc.	Grieshaber Mfg. Co., Inc.
Fresenius Kabi	Gentex Pharma	gSource, LLC
Fenwal, Inc.	Genus Medical Technologies, LLC	G Surgical LLC
Fresenius Pharma	Genzyme Corporation	GTI Diagnostics
Fresenius AG	George Medical, LLC	G.T. Laboratories, Inc
Fricke International Inc	George Taub Products	Guardian Angel Products, Inc.
Frontier Medical Devices, Inc.	George Tiemann & Company	Guidant Corporation
Frye Electronics, Inc.	Gergens Orthodontic Lab	Cardiac Rhythm Management
FTT Medical, Inc.	Gergens Sleep Lab	Guidant CVS
	Gesiva Medical, LLC	

Registered Labelers

Vascular Intervention	Hedwin Corp.	Impact Products
Guided Therapeutics Inc.	Helena Laboratories, Inc.	ImpediMed Limited
Gulden Ophthalmics Inc.	Hemedex, Inc.	ImpediMed Inc.
GWR Medical, Inc.	Hemostasis LLC	Imperative Care Inc
Gynecare, Inc.	Henry Schein, Inc.	Imperial Medical Technologies, Inc.
Gynex Corporation	Henry Troemner, Inc.	Impeto Medical, Inc.
Gyrus Ent	Heraeus Kulzer, Inc.	Implant Innovations, Inc.
Gyrus Medical	Dental Products Group	Implant Logistics, Inc.
Gyrx, LLC	Heuer Time & Electronics Corp.	Implantech Associates, Inc.
Endox LLC	Hexim Pharmaceuticals Inc.	InBios International Inc.
H & O Inc.	Higi Sh LLC	Incisive Surgical, Inc.
H W Andersen Products, Inc.	Hill-Rom, Inc.	Incite Innovation, LLC
Hager & Werken	Medic PRN	Independent Medical Co-op (IMCO)
Hager Worldwide	HK Surgical, Inc.	Ind. for the Blind and Visually Impaired
Hamamatsu Corp.	Hobbs Medical, Inc.	Indian Wells Medical, Inc.
Photonics Management Corp.	Home Access Health Corporation	InfoBionic Inc
Hankook Latex Gongup Co. Ltd.	Hospira, Inc.	Infraredx, Inc.
Calatex Inc.	Hospital Mktg. Services Co., Inc.	InFront Medical LLC
Hantel Technologies, Inc.	Hotspur Technologies, Inc.	Infusive Technologies, LLC
Hanson Medical, Inc.	Howard Medical Company	Ingen Orthopedics, LLC
Harbor Medical Devices, Inc.	Howard Young Medical Center	Innara Health (formerly KC BioMedix)
Harbor Safety Products Group LLC.	Hudson Respiratory Care, Inc.	Inneroptic Technology, Inc.
Hard Mfg. Co.	Hu-Friedy Mfg. Company	Innerspace Corp.
Hardwood Products Co.	Hu-Friedy Mader Medical	InNeuroCo, Inc.
Harry J. Bosworth Co.	Human Motion and Control	InnoMed Technologies
Harvest Dental Products LLC	Huntleigh Technology, Inc.	Innovasis, Inc.
Harvest Technologies	Huntleigh Healthcare, Inc.	Innovasive Devices, Inc.
Havel's, Inc.	Huot Instruments, LLC	Innovasive Inc.
Hawaii Medical, LLC	HWI	Innovative Healthcare Corporation
Hayes Handpiece Co.	Hycor Biomedical Inc	Innovative Neurotronics, Inc.
Health Care Logistics, Inc.	Hydrocision Inc	Hanger Orthopedic Group, Inc.
Health Dent'I, LLC	Hydrotech Enterprises	Innovative Surgical Designs
Health Services Corp. of America	Hy-Tape International	Innovative Therapies, Inc.
Healthcare Materials Network	Iconacy Orthopedic Implants, LLC	Inova Diagnostics, Inc.
Healthcare Products Plus	Iconlab, Inc.	Inova Labs
Healthlink, Inc.	ICP, Inc. dba Dental City	Inovise Medical, Inc.
Healthmark Industries Co.	ICP Medical	INRAD, Inc.
Health-Mor Industries, Inc.	ICU Medical, Inc.	Insert Molding Solutions Inc.
Health-Mor Personal Care Corp.	Ideal Implant Incorporated	Inspirstar Inc.
HealthMyne, Inc.	IDEV Technologies, Inc.	Instrumentation Industries Inc.
HealthyWiser LLC	IEC - Innovative Endoscopy Components, LLC	Integra Lifesciences Corporation
Heart Imaging Technologies, LLC	IlluminOss Medical Inc.	Integra Luxtec, Inc.
Heart Technology, Inc.	Imaging Biometrics, LLC	Integra Life Sciences
Heart Ware, Inc.	Imagyn Medical Tech	Integra Pain Management
Hearten Medical, Inc.	Imbed BioScience, Inc.	Integra Radionics
Heartport	Immuno Concepts	Integrated Biomedical Technology
HeartVista, Inc.	Immuno-Biological Laboratories Inc	Integrated Dental Systems
		Integrated Medical Technologies, Inc.

Registered Labelers

CPAC Equipment, Inc.	JBC & Company (Elite Syndication Incorporated)	Kerberos Proximal Solutions, Inc.
Integrity Life Sciences, LLC	JBC Corp.	Kerr Corporation Alden
Interflo Medical	Jedmed Instrument Company	Key Electronics
International Biophysics Corp.	Jensen Tools, Inc.	Keystone Industries Mizzy, Inc.
International Business Solutions Alliance	Jeremiah Sales Professional Inc.	Keystone Manufacturing
International Equipment Company	Jewel Preceision Sheet Metal & Machining, Inc.	Kids Med Inc.
International Hospital Products, Inc.	Johnson & Johnson	Kimberly Clark Corp. Health Care Products Group
International Medical Development	Advanced Sterilization Products	Kinamed, Inc.
International Medical Devices, Inc.	Codman & Shurtleff, Inc.	Kinetic Concepts, Inc.
International Medical Distributors, Inc.	Cordis Biot Div.	King Pharmaceuticals, Inc.
International Medical Industries, Inc.	Cordis Miami Div.	Kips Bay Medical, Inc.
International Medical Research & Design	Cordis Roden Div.	Kirschner Medical Corp.
International Win, Ltd.	DePuy Acromed	K-Laser USA LLC
Interpore Cross International	DePuy Mitek	Kleen Test Products
Interpore Orthopaedics, Inc.	Independence Technology	KMedic
Intersect ENT	J&J Dental Care	Knoll Pharmaceutical Co.
Intersect Partners LLC	J&J Hospital Services	Koehler Instrument Co., Inc.
Intra-Lock International, Inc.	J&J Consumer Products Co.	Korr Medical Technologies Inc
Intraluminal Therapeutics	J&J Medical, Inc.	Kronus, Inc.
Intra-Sonix, Inc.	J&J Medical (China) Ltd	KUB Technologies Inc.
Intrinsic Interventions Inc.	J&J Professional, Inc.	Kyowa Kirin Inc
Intrinsic Therapeutics, Inc.	Janssen Pharmaceutical, Inc.	Kyphon, Inc.
Intuitive Imaging Informatics, LLC	Lifescan, Inc.	L&R Mfg. Company
Intuitive Surgical, Inc.	McNeil Pharmaceutical Canada	Lab Depot, LLC
Invitro Systems, Inc.	OMJ Pharmaceuticals, Inc.	Labconco Corporation
Invotec International, Inc.	Ortho Clinical Diagnostics	Lab-Line Instruments, Inc.
Invuity, Inc.	Ortho-McNeil Pharma. Corp.	Laborie Medical Technologies
I Play., Inc.	Sarl	Lacrimedics, Inc.
IQ Implants Ltd.	Therakos	Lafayette Pharma., Inc.
IT3 Medical, LLC	Jordco, Inc.	Lake Hospital Systems, Inc.
Irrimax Corporation	JS Dental Manufacturing, Inc.	Lake Region Mfg., Inc.
Irvine Biomedical, Inc.	Justrite Manufacturing Company	Lakeside Mfg., Inc.
IsoAid, LLC	K2M, Inc.	Lamico, Inc.
Isolyser Company, Inc.	K5 Brands, LLC	Lang Dental Mfg. Co., Inc.
IsoRay Medical, Inc.	Kaia Health Inc	Lares Research
Ivera Medical	Kalitec Direct, LLC	Laschal Surgical
Ivoclar Vivadent, Inc.	Kapp Surgical Instrument, Inc.	Latexx Partners Berhad Medtexx Partners, Inc.
Ivy Sports Medicine, LLC	Kareco International, Inc.	Lazarus Medical, LLC
J & R Enterprises, Inc.	Katena Products, Inc.	LC Medical Concepts, Inc.
Jac-Cell USA Inc.	Kator LLC	LD Technology LLC
Jaece Industries, Inc.	KC Biomedix	LED Intellectual Properties LLC
James River, Inc. Health Care Division	K-C Medical, Inc.	LED Technologies, Inc.
James W Daly, Inc.	KCI New Technologies, Inc. Kinetic Concepts, Inc.	Lee Memorial Hospital
Japan Medical Dynamic Marketing, Inc. Ortho Development Corp.	Keller Medical Specialties, Inc.	Leeder Group, Inc.
Jason Marketing Company	Kenad SG Medical, Inc.	
	Kendro Laboratory Products	
	Kennedy Memorial Hospitals	
	Kensey Nash Corporation (dba - DSM BioMedical)	
	Kent Laboratories Inc.	
	Keos	

Registered Labelers

Legend Spine LLC	Maclin Power Inc.	Mederi Therapeutics Inc.
Leggero LLC	MAC Medical Inc.	Medex, Inc.
Leica	Maersk Medical, Inc.	Medex Medical Mktg.
Optical Products Division	Magellan Biosciences	Med-Fit Systems, Inc.
Leomed, LLC	Dynex Technologies	Medge Platforms, Inc.
LGM International, Inc.	ESA Biosciences	Mediaid Inc.
Liberty Medical, Inc.	Magnatone Hearing Aid Corp.	Medgyn Products, Inc.
Lifecell Corporation	Mako Surgical Corp.	Mediblu Medical LLC
Life Corporation	Mallinckrodt Baker, Inc.	Medica Holdings, LLC
Life Instrument Corp.	Mallinckrodt Chemical	Medical Action Industries, Inc.
Life Science Outsourcing, Inc.	Mallinckrodt Anesthesia Products	Medical Chemical Corporation
Lifesignals, Inc.	Mallinckrodt Anesthesiology	Medical Concepts Dev., Inc.
LifeSouth Community Blood Centers, Inc.	Mallinckrodt Diag. Products Div.	Medical Designs LLC
Lifestream International, Inc.	Mallinckrodt Medical, Inc.	Medical Device Technologies, Inc.
Lifestream Purification Systems	ManaMed	Angiotech Pharmaceuticals, Inc.
Life-Tech, Inc.	Mann Chemical Corp.	Medical Devices International
LifeVac LLC	Maramed Orthopedic Systems	MDI Plasco, Inc.
Liger Medical LLC	Marie Reiko Inc.	Medical Facets NC, LLC
Light Age, Inc.	Mark Clark	Medical Graphics Corporation
Lighthouse for the Blind	Maryland Plastics, Inc.	Medical Illumination Int'l., Inc.
Lilli Pads Inc	Masimo Corporation	Medical Imaging Applications, LLC
Linvatec	Mason Tayler Med. Products Corp.	Medical Informatics Corp
Hall Surgical	Masterlink	Medical Infusion Technology
Lin-Zhi International, Inc.	Math Resolutions	Medical Instrument Dev. Labs, Inc.
Laboratory Corporation of America	Matrx Medical, Inc.	Medical Inventors Corporation. Inc.
Little Rapids Corporation	Matrix Surgical Holdings, LLC	Medical Laboratory Automation, Inc.
Lohmann GmbH & Co.	MaxiFlex LLC	Medical Latex Corp.
Carapace, Inc.	Max Mobility, LLC	Medical Products Laboratories, Inc.
Loma Vista Medical	Maxtown Medical Corp. LLC	Medical Resources Int'l.
Lone Star Medical Products, Inc.	Maxxim Medical	BNT Co., Inc.
Lone Star Technologies	Containment Products	Medical Solutions International, Inc.
Loon Medical, Inc.	Medical Diagnostics	Medical Technology Products Inc.
Lorrex Health Products	Medical Nonwovens & Gloves	Medication Delivery Devices
Louisville APL Diagnostics, Inc.	Sterile Trays/ Non-sterile Kit	Medicochoice (Owens & Minor)
Louisville Pharmacy	Maveron Health	Mediflex, Division of Flexbar Machine Corp.
LSI Solutions Inc.	Maytex Corporation	Medifocus, Inc.
Lucas Medical Inc.	MC10, Inc.	Medigroup Inc. / Janin Group
Luitpold Pharmaceuticals, Inc.	McGinley Orthopaedic Innovations LLC	Medipoint, Inc.
Lumend, Inc.	MCM Environmental Technologies Ltd	Medisono LLC
Lumiquick Diagnostics, Inc.	GMS Marketing	Meditech International Corp.
Lumitex Medical Devices, Inc.	MD Industries, Inc.	Meditech Spine, LLC
Surgical Division	MD Technologies Inc.	Medivance, Inc.
Lutech Industries, Inc.	Measurement Specialties, Inc.	Medivest, Inc.
Luwi, LLC	Medcanica, Inc.	Medline Industries, Inc.
LYMOL Medical Corp.	Medegen, Inc.	Medlogic
LZR7 Inc	Medegen Medical Products	Mednum Corporation
M2S, Inc.	Medela Healthcare	Medovex Corporation
	Medennium, Inc.	Medrad, Inc.
	Eyepx LLC	
	Medental International Inc	

Registered Labelers

Medscience Research Group, Inc	MicroPhage, Inc.	M-Pact Worldwide, LLC
MedShape, Inc.	MicroPort Orthopedics, Inc.	MPL Technologies
Medstreaming	Micro-Scientific Industries, Inc.	MPS Acacia
Medtek Devices, Inc. Buffalo Filter	Microtherapeutics, Inc.	MPS Medical, Inc.
MedTek Skin Care Inc	Microvention, Inc.	MRaudio Inc
MedTrak VNG, Inc.	Microvision, Inc.	MRLB International, Inc.
Medtrex Incorporated	Micrus Corporation	MTI Precision Products
Medtronic, Inc. Biotek International SPA Blood Systems Cardiopulmonary Cardiorhythm CAS Venture DLP Drug Administration Systems Interstim Venture Interventional Vascular Inc Medtronic Bio Medicus Medtronic, Inc (CPRA) Merocel Scientific Division Neurological Division Pacing Business Unit Physio-Control Corp. Vascular Division Vitatron, Inc. Xomed	Midwest Textiles, Inc.	Musculoskeletal Transplant Foundation
	Migun Life, Inc.	My-Cardia (USA) Inc
	Millennium Biomedical, Inc.	MyCardio LLC
	Millennium Dental Technologies, Inc.	Myco Medical
	Millennium Surgical	Myelotec, Inc.
	Miltex, Inc.	Mynosys Cellular Devices
	Milton Roy Company Analytical Product Division	Myotronics Noromed Inc.
	Mimedx Group, Inc.	Myocardial Solutions
	Mindframe, Inc.	MytaMed, Inc.
	Mindways Software, Inc.	Nanogen, Inc.
	Minnesota Resuscitation Solutions LLC dba Advanced CPR Solutions	Nanoscale Materials, Inc.
	Minnow Medical, Inc.	Nanosphere, Inc.
	Minrad, Inc.	Nashville Surgical Instruments
	Mirecal, LLC Remicalm, LLC	Nasiff Associates, Inc.
	Misonix, Inc.	National Distribution and Contracting
	Mitre Medical Cop Corp	National Medical Products, Inc.
	MIVI Nueroscience, Inc.	National Standard Company Medical Products Division
	Mizuho OSI, Inc.	Natus Medical, Inc.
	MM Herman & Associates, LLC Flu Armour Herman Products	Nellix, Inc.
	MMS, LLC	Neocare
	Moberg Research, Inc.	NeoChord Inc.
	Mobius Therapeutics, LLC	Neodevices, Inc.
	Modal Manufacturing, LLC	Neo Medical Inc.
	Modec, Inc.	Neotract, Inc.
	Molded Products	Nephros Inc.
	Molded Products, Inc.	Neptune Products, Inc.
	MolecularMD Corp	Netech Corporation
	Molecular Biometrics, Inc.	Neucoll
	Momelan Technologies, Inc.	Neuhaus Laboratories, Inc.
	Monarch Labs	NeuroChaos Solutions, Inc.
	Moore Business Forms, Inc.	Neuro-Fitness LLC
	Mortan, Inc.	Neuro Kinetics Inc.
	Mortara Instrument, Inc.	Neurolumen LLC
	Motloid/Yates & Bird Bird-X, Inc.	Neuronetrix Solutions, LLC
	Moximed, Inc.	NeurOptics, Inc.
		Neurorecovery, Inc.
		Neurotron Medical Inc.
		Neurovasx, Inc.
		Neurovision Medical Products, Inc.

Registered Labelers

Nevro	Omega Surgical Instruments, Inc.	OT Medical, LLC
New Wave Surgical Corp.	OMNA	Otoharmonics Corporation
Newby/Coombs, LLC	Omni International, LLC	Ototronix, LLC
Newell Rubbermaid, Inc.	Omni-Flow, Inc.	Owens-Illinois, Inc.
Rubbermaid Commercial Products, LLC	Omnisonics Medical Technologies	Owens Brigan
Newman Medical	Omni-Tract Surgical	Owens-Illinois Health Care Group
Newtex Industries, Inc.	Integra Life Sciences	Pacira Pharmaceuticals, Inc.
Nexcore Technology	OMT LLC	Packaging Services Corp. of Kentucky
Nextremity Solutions, LLC	One Cell Systems, Inc.	Olsen Medical
Next Science, LLC	Ongoing Care Solutions	Pall Corp
Nexus CMF, LLC	Onkos Surgical	Pall Biomedical Products Co.
Nexus Medical, LLC	Opa Dental, LLC	Palmero Health Care
Nexus Spine	Open Implants, LLC	Palm Springs Partners, LLC dba Maxim Surgical
Niche Medical	OphthalMed LLC	Palo Alto Health Sciences
Ni-Med, Inc.	Ophthalmic Innovations International, Inc.	Pantheon Spinal LLC
Nivo Industries Inc.	Ophthalmic Solution Inc.	Panther Orthopedics Inc
Nmt Medical, Inc.	Optical Integrity Inc.	Paragon Vision Sciences, Inc.
Nobles Medical Technology II	Optical Radiation Corp.	Parascript, LLC
Nordent Manufacturing Inc.	Opticon Medical	Parcus Medical, LLC
Norfolk Medical Products, Inc.	Optimedita Corporation	Pare Surgical, Inc.
Norma Tec, Inc.	Optimotion Implants, LLC	Park Dental Research Corp.
North Coast Medi-Tek ,Inc.	Opus Medical, Inc.	Parkell, Inc.
Northeast Monitoring, Inc.	Ora Innovations, Inc.	Parker Hannifin Corp.
Northeast Scientific, Inc.	Orbus Medical Technologies, Inc.	Parker Medical Associates
Norvell, LLC	Origen Biomedical	Parts Warehouse
Body Invest, LLC	Ortho Solutions, LC - Dynaflex	ParvoMedics Inc
Novarad Corporation	Ortho-Tain, Inc.	Pascal Company, Inc.
Novomedics, LLC	Ortho Technology	Patient Pocket LLC
NovoSci	OrthoCircle	Patterson Dental Company
Novoste Corporation	Orthofix Inc.	Patton Surgical Corporation
Nucryo, Inc.	OrthoMedFlex LLC	PAVmed Inc.
Numed, Inc.	Orthomerica Products, Inc.	PDI/Professional Disposables Int'l.
Numia Medical Technology, LLC	Orthopaedic Implant Company	Pearson Dental Supply Co.
Nu Radiance, Inc.	OrthoPediatrics Corp.	Peerbridge Health, Inc
Nurse Assist, Inc.	Orthopedic Designs North America, Inc.	Peerless International, Inc.
Nutek Orthopaedics, Inc.	OrthoScan, Inc.	Pelikan Technologies, Inc.
Nutriseal	Oscor Inc.	Pemco Inc.
Nxstage Medical, Inc.	Osprey Medical Inc.	Pennsylvania Engineering Company
Oasis Medical	Osseolink USA LLC	Pentair Filtration Solutions LLC
OBP Corporation	Osseon LLC	Engineered Filtration
OCO Biomedical, Inc.	Osseon Therapeutics Inc.	Penumbra, Inc.
OcuJect, LLC	Osseus Fusion Systems, LLC	Percutaneous Systems, Inc.
Oculus Surgical, Inc.	Osteogenics Biomedical, Inc.	Perfecseal
Ohaus Scale Corporation	OsteoReady LLC	Medi-Plus
Olson Medical Sales, Inc.	Ostex International, Inc.	Perigon Medical Distribution Group
Olympus Biotech Corporation	Ostia Corporation	PerioEndoscopy LLC dba OraVu
Omega Medical Products Corp.	Ostia Solutions, LLC	Peripheral Visions, Inc.

Registered Labelers

PerMedics, Inc.	Prescient Logistics, LLC	QI Imaging, LLC
Pfizer Hospital Products Group, Inc.	Preventive Technologies	Qorpak
American Medical Systems, Inc.	Prevent-Plus LLC	QRS Diagnostic, LLC
Schneider (USA)	Primotec LLC	Quality Assembly & Logistics LLC
Shiley, Inc.	Principle Business Enterprises	Quantimetrix Corporation
Valleylab, Inc.	Priority Environmental Solutions Inc. dba PRO1TEK	Quantum BioEngineering, Ltd.
Pfizer Warner Lambert Co.	Prismatik Dentalcraft, Inc.	Quintus, Inc.
Parke-Davis Division	Prism Clinical Imaging, Inc.	QView Medical, Inc.
Phalanx Innovations LLC	Procedure Products, Inc.	R Medical Supply Inc.
Pharmacia, Inc.	Procept Biorobotics Corporation	R-Med, Inc.
Pharmacia Ophthalmics	Professional Hospital Supply, Inc.	R2 Dermatology
Pharma-Plast, Inc.	Professional Medical Products	R4 Vascular, Inc.
Pharma-Plast Denmark	Professional Products, Inc.	Radius, LLC
Pharma-Plast USA	Government Sales Division	Radius Medical Technologies, Inc.
Phase One Medical	Prograft Medical, Inc.	Radtech, Inc.
Philips Medical Systems	Progressive Dynamics, Inc.	RAMM Technologies LLC
Phoenix Dental, Inc.	Proma, Inc.	RAMVAC Dental Products, Inc.
Pilling Weck	Promex Technologies, LLC	Ramsey Diagnostics Corp
Weck Closure Systems	Propper Manufacturing Co., Inc.	Ranfac Corporation
Pinnacle Products, Inc.	ProTech Professional Products, Inc.	Rapid Reboot Recovery Products
Pintler Medical, LLC	Protect U Guard, LLC	RD Medical Manufacturing, Inc.
Pioneer Surgical Technology	Protekmed, LLC	Reckitt & Colman, Inc.
Plasdent Corporation	Providence Medical Technology, Inc.	R & C Probrands
Plastek Industries, Inc.	PSC of Kentucky	Recovery Force
Plasti-Products, Inc.	Olsen Medical	Relda LLC dba Dermatec Direct
Pluromed, Inc.	PSS World Medical	Red Bird Service
Poly Vac	Gulf South Medical Supply	Ricca Chemical Company, LLC
Polytechnic Resources, Inc.	PT Eka Wira Asia	Redicare LLC
Pope Scientific, Inc.	Puerto Rico Hospital Supply, Inc.	Reed Technology & Information Svcs, Inc.
Porex Technologies Corp. of Georgia	Pulmonetic Systems, Inc.	Reflow Medical Inc.
Porex Surgical, Inc.	Viasys Healthcare, Inc.	ReGear Life Sciences, LLC
Porton Diagnostics, Inc.	Pulmonx, Inc.	Regenerative Processing Plant, LLC
Porton International PLC	Pulpdent Corporation	Regent Hospital Products, Ltd.
Posey Company	Pulse Biosciences	London International Group PLC
Post Medical, Inc.	Pure Life Solutions	Reliance Mobility LLC
Pouch Support Systems, Inc.	PureLife LLC	Reliance Orthodontic Products, Inc.
Power Medical Interventions, Inc.	PureWay Compliance, Inc.	Remicalm, LLC
pNeo LLC	Puritan-Bennett Corporation	Renovis Surgical Technologies, Inc.
Practicewares Dental Supply	Bennett Group	ReNovo, Inc.
Precision Dynamics Corp.	Boston Division	Renovo Life LLC
Precision Laboratory Plastics, Inc.	Cryogenic Equipment Division	Reproductive Solutions, Inc
Precision Scientific, Inc.	Ireland, Ltd.	Republic Spine, LLC
Precision Systems, Inc.	Medicomp, Inc.	Reshape Lifesciences
Precision Vascular Systems	Oxygen Concentrator Division	ReShape Medical Incorporated
Premier Biotech Inc.	Portable Ventilator Division	Respironics, Inc.
Premier Dental Products Company	Puritan Group	Restorative Therapies, Inc.
Premier Heart, LLC	Pursuit Vascular, Inc.	Restore Medical, Inc.
Premium Plastics, Inc.	Pymah Corp.	
Presby Corporation	ATI Division	
	QBC Diagnostics	

Registered Labelers

Rex Implants LLC	Scientific Pharmaceuticals	Silex Medical, LLC
Rex Medical LP	Scientific Safety Solvents	Simpact, LLC
Rhausler, Inc.	Scieran Technologies, Inc.	Simpex Medical
Rhythmink International, LLC	Scigen Scientific	SinuSys Corporation
Ribbond, Inc.	Scion Cardio-Vascular, Inc.	SiO2 Nanotech, LLC
Ricca Chemical Company, LLC	Scitech Dental, Inc.	Siris Medical, Inc.
Richard-Allan Medical Industries Image & Medical Technologies	Scivolutions, Inc.	Sirona Dental, Inc.
Rinn Corp.	Scott's Dental Supply	Skedco, Inc.
Rivanna Medical	SDI Diagnostics, Inc.	SkinStitch Corp.
Riverain Technologies	Seamless Hospital Products Co.	Sklar Corporation
Riverside Community Hospital	Sea Spine, Inc.	Slater Endoscopy, LLC
RJL Systems	SeaSpine Orthopedics Corporation	Smart Medical Technology, Inc.
Roche Diagnostic Systems	IsoTis Orthobiologics, Inc.	SmartPractice, Inc.
Rox Medical, Inc.	Second Sight Medical Products, Inc.	Smartcare
Roxane Laboratories, Inc.	Secure Surical Corporation	Smartpill Corporation
Roxwood Medical, Inc.	Securisyn Medical, LLC	Smith & Nephew
Royal Biologics	Semler Technologies, Inc.	Endoscopy Division
Royce Medical	Sempermed USA, Inc.	Orthopaedic Division
Roydent	Senorx, Inc.	Orthopaedics AG (Switzerland)
Rumex International Co.	Sentreheart, Inc.	Orthopaedics Co., Ltd (Beijing)
S.A. Instrumentation Difra	Septodont, Inc.	Orthopaedics GmbH (Germany)
SAC LLC	Seradyn, Inc.	Orthopaedics, Ltd.
Orange Surgical Instruments	Fisher Scientific International	United Wound Management Division
Sacred Heart Medical, Inc.	Serene Medical Inc	SMK Imaging LLC dba ImageWorks
Sadra Medical Corporation	Serim Research Corporation	SML - Space Maintainers Laboratories
Safco Dental Supply Co.	Shamrock Scientific Specialty Systems	SNAP Diagnostics LLC
Safety Medical International, Inc.	Shape Medical System	Soberlink Healthcare LLC
Saf-T-Med	Sharklids Eye Gear	Sodium Systems LLC
Sage Products, Inc.	Sharn Anesthesia	Sofregen Medical Inc
Saint Gobian Performance Plastics	Sharon Metal Stamping Corp.	Solina Medical, Inc.
Sakura Finetek USA, Inc.	Walk on Air	Solo-Dex LLC
Salient Imaging, Inc.	Sharp Fluidics, LLC	Solutions Inc.
Samco Scientific, Inc.	Sharps Terminator, LLC	Somahlution LLC
Sandhill Scientific	Sheldon Manufacturing, Inc.	Somatics, LLC
Sanovas, Inc.	Shepard Medical Products	Somnetics International
Santa Barbara Imaging Systems	Sherwood Pharmaceutical Co.	Somnus Medical Technologies
Saphena Medical	Shockwave Medical Inc.	Sonavex, Inc.
Savannah River Mills, Inc.	Shoulder Innovations	Sonic Innovations, Inc.
SBW Medical Products, Inc.	Si Bone, Inc.	SonoCine Inc.
Scandius Biomedical, Inc.	Sicage, LLC	Sonotech, Inc.
Schleicher & Schuell, Inc.	Sicor, Inc.	Sontec Instruments, Inc.
Schwarz Pharma	Gensia Pharmaceuticals, Inc.	Sony Corporation
Kremers Urban Co	Sienco, Inc.	Sorb Technology, Inc.
Science, Inc.	Sigma Rx LP	Sorin Biomedica
Scientia LLC	Sigma Supply & Distribution, Inc.	Cobe Cardiovascular UK
Scientific Equipment Products Co.	Signal Medical Corporation	Sota Medical Products
	Silicon Valley Medical Instruments, Inc.	Sorin Group,USA, Inc.
		Sourceone Healthcare Technologies
		South East Instruments Corporation

Registered Labelers

Southeast Signal, Inc	St. Jude Medical	Sun Nuclear Corporation
Southland Medican LLC	Diagnostic Division, Inc.	Sun Scientific, Inc.
Spacelabs Medical, Inc.	St. Jude Medical CRMD	Sun-Med
Span-America Medical Systems, Inc.	St. Peter Hospital	Sunoptic Technologies
Sparta Surgical Corporation	St. Vincent Hosp. & Hlth. Care Ctr.	Sunquest Information Systems
Sparta Maxillofacial Products, Inc.	Stabiliz Orthopaedics LLC	Superdimension, Inc.
Spartan Micro, Inc.	Staco Energy Products Company	Superior Health Care Group, Inc.
Spatz FGIA Inc	Standard Register	Superior Surgical Products
Spaulding Clinical Research	Advanced Medical Systems	SureTek Medical
Spaulding Medical	Starchem, Inc.	Surgical Direct
Specialized Health Products	Starion Instruments	Surgical Site Solutions, Inc.
Specialty Appliance Works, Inc.	Starline Dealers Association	Surgical Specialties Corporation
Specialty Health Products, Inc.	Statcorp, Inc.	Surgical Warehouse, Inc.
Specialty Surgical Instrumentation, Inc.	Stellar Lasers, LLC	Surgicot, Inc.
Specialty Surgical Products, Inc.	Stellen Medical, LLC	Value Medical Products, Inc.
Specialty Water Technologies, Inc.	Step Forward Co.	Surgikor
Spectra Medical Devices, Inc.	Stereotaxis, Inc.	Surgimedics, Inc.
Sprectramed	Steris Corporation	Denver Biomedical, Inc.
Spectramed, Inc.	Amsco Canada - Ingram & Bell	Surgi-Pak, Inc. dba National Hospital
Spectranetics Corporation	Amsco Service Co. - Ingram & Bell	Packaging
Spectrum Designs Medical	Stern Metals, Inc.	SurgiQuest, Inc.
Spectrum Designs Inc.	Sterngold	Surx, Inc.
Spectrum International, Inc.	Stiehl Tech LLC	Sutura Inc.
Spectrum Medical Industries, Inc.	Stingray Surgical Products, LLC	Suture Concepts, Inc.
Spinal Kinetics	Stinson Orthopedics Inc.	Svelte Medical Systems
SpinalMotion, Inc.	Storz-GmbH	Sweet Spot Diabetes Care
Spinal Resources Inc.	American Cyanamid	Sybron Chemicals
Spinal Simplicity, LLC	Streck Laboratories, Inc.	Clinical Technology Div.
SpineCraft	Stradis Medical DBA Stradis Healthcare	Sybron Corp.
SpineNet, LLC	Strata Skin Sciences, Inc.	Analytical Products Div.
Spineology Inc.	Structure Probe, Inc.	Barnstead Co.
SpiralTech Superior Dental Implants	SPI Supplies Division	Mediatech Div.
Spire Corporation	Stryker Corporation	Panorama Plastics
Spire Biomedical	Dimso Division	Sybron Endo
Spyder Medical	Stryker Ascent	Thermolyne Corp.
SPR Therapeutics, LLC	Stryker Endoscopy Division	Sybron Corpnalge Nunc Int'l.
SRI/Surgical Express, Inc.	Stryker Dental	Apogent
Sroufe Healthcare Products	Stryker Global Quality & Operations	Sybron Dental Specialties
Remington Products	Stryker Howmedica Osteonics	Ormco
SRS Medical Systems, Inc.	Stryker Instruments	Symmetry Medical USA, Inc.
SSCOR Inc.	Stryker Medical	Synergetics USA, Inc.
SS White Burs, Inc.	Stryker Orthopaedics (Otis Med)	SynergEyes, Inc.
St. Francis Regional Medical Center	Stryker Osteo AG	Synergy Biomedical, LLC
St. Francis-St. George Hospital	SuitX	SynGen, Inc.
St. George Technology, Inc.	Sulzer Carbomedics	Syntermed, Inc.
St. Gobain Performance Plastic	Sulzer Medica	Synthasome, Inc.
St. Johns Mercy Medical Center	Sulzer Intermedics USA	Synthemed, Inc.
	Summit Industries LLC	Syntheon, LLC
	Summit Medical Center	ID LLC
	Summit Spine LLC	Synthes
	Sun Capsule Inc.	
	Sun Medical Inc.	

Registered Labelers

Synthes Spine Company LP	The Torrent Corp.	Tri-Anim
Synthes USA	The Upjohn Company	eValueMed
Maxillofacial Division	Upjohn Pharmaceuticals	Magnus
SZY Holdings, LLC	Theradome Inc.	Tri-Anim Surgical Solutions
Ever Ready First Aid	Theravant Corporation	Tri-Ject International Corp.
T2 Biosystems, Inc.	Thermo Cardiosystems, Inc.	Trimed, Inc.
T.C. Dental Products, Inc.	Thermo Fisher Scientific	Trimedyn, Inc.
Talladium Inc.	Trek Diagnostics	Trimira LLC
Tandem Medical, Inc.	Thermopectix, Inc.	Remicalm LLC
Tangible Science LLC	Thermoplastic Comfort Systems Inc.	Trinity Medical Implants, Inc.
Tapmedic LLC	ThermoTek, Inc.	Trinity Sterile, Inc.
Taut, Inc.	Think Surgical, Inc.	Trireme Medical, Inc.
Taylor Bio-Medical, Inc.	Thomas Jefferson University	Tri-Star Medical
Tecator, Inc.	Thomas Scientific	TriVascular, Inc. (A Wholly Owned Subsidiary of Endologix, Inc.)
Techdevice Corporation	Thompson Surg. Instruments, Inc.	Trudell Marketing International
Technical Products, Inc.	Three Palm Software	Northgate Technologies, Inc.
TeDan Surgical Innovations, LLC	Tian Medical LLC	Truemed Group LLC
Tekia, Inc.	TIDI Products	Turenne Pharmed Co.
Teledyne Technologies, Inc.	Tiger Supply Inc.	Turenne & Associates LLC
Teleflex CT Devices, Inc.	Timemed Labeling Systems	Tyber Medical LLC
Tele-made Disposables Inc	Timrex Corporation	Tyco Healthcare
Tempur-Pedic North America, LLC	Tissue Link Medical, Inc.	Tyco Healthcare Ludlow
Tendyne Holdings Inc.	Titan Spine, LLC	Typenex Medical, LLC
Tenet Health	Titus Medical, LLC.	UARCO, Inc.
TENSproducts, Inc	Tivic Health Systems Inc	UCLA Medical Center
TeraRecon, Inc.	TMJ Solutions, Inc. dba TMJ Concepts	Uhler Dental Supply, Inc.
Terumo Medical Corp.	TOMY International, Inc.	Ultradent Products, Inc.
Terumo Europe N.V.	Top Quality Manufacturing, Inc.	Ultralite Enterprises Inc.
Tessek	Top Spins, Inc.	Ultrasound Medical Devices, Inc. dba Epsilon Imaging, Inc.
TestSmarter	Topcon Medical Laser Systems, Inc.	Unetix Vascular Inc.
Thayer Intellectual Property, Inc.	TPC Advanced Technology, Inc.	Unicare Biomedical, Inc.
The Alger Company, Inc.	Trademark Medical LLC	Uniforms Manufacturing, Inc.
The Anspach Effort, Inc.	Transamerica Delaval Med. Prod.	Unimed Surgical Products, Inc.
The Argen Corporation	TransAmerican Medical Imaging dba of Canyon Ridge Resources, LLC	UniPak Medical Corporation
The Burrows Company	Transamerican Technologies International	Unique Technologies, Inc.
The Cheshire Medical Center	Transdermal Cap Inc.	United States Surgical Corp.
The Coopers Companies, Inc.	TransEnterix	HTR Sciences
Cooper Surgical, Inc.	Transgenomic, Inc.	Surgical Dynamics
The Gerresheimer Group	Transmedics	Tyco Healthcare
Kimble Glass	Transtracheal Systems, Inc.	Universal Medical Inc.
Kontes Glass, Inc.	Transvascular Inc.	Universal Meditech Inc.
The GID Group, Inc.	Transverse Medical Inc.	University of California Med. Ctr.
The Hygenic Corp.	Tredegar, Inc.	University of Michigan Hospitals
The Morel Company	Therics, Inc.	UreSil LLC
The Procter & Gamble Company	TreyMed, Inc.	Urologix, Inc.
Norwich Eaton Pharmaceuticals	Tri State Distribution, Inc.	USA Think Inc.
The Standing Company		USGI Medical
The Texwipe Company		US Endoscopy, Inc.

Registered Labelers

US Medical Innovations, LLC	Visionary Medical Supplies, Inc.	White Square Chemical, Inc.
US Medical Instruments, Inc.	Visioneering Technologies, Inc.	Whitney Products, Inc.
US Spinal Technologies, LLC	Visitec Company	Ascent Medical Corp.
Utah Medical Products, Inc.	Vistalab Technologies	WilMarc Medical, LLC
V2K Medical, LLC	Vital Signs, Inc.	Windstone Medical Packaging
Vacalon Company, Inc.	Vitronix, Inc.	Winprobe Corporation
Vadus, Inc.	VLV Associates, Inc.	WishBone Medical Inc.
Valeris Medical, LLC	Voland Corporation	Wolf X-Ray Corp.
Vahalla Scientific, Inc.	Volcano Therapeutics, Inc.	Flow Dental
Vapotherm, Inc.	Vomaris Innovations, Inc.	Flow X-Ray Corp.
Vascular Designs, Inc.	Vortex Surgical, LLC	Wolfe Tory Medical, Inc.
Vascular Solutions	Vorum Research Corporation	World Class Technology Corporation
Vascular Technology	VQ Company, LLC	Wright Medical Technology, Inc.
Vastek	VuCOMP, Inc.	Wyant Healthcare
Vastrac, LLC	VWR International Co.	Wy'east Medical Corp.
Vector, Inc.	W A Baum Co., Inc.	Xanacare Technologies, LLC
Velocity Medical Solutions	W L Gore & Assoc., Inc.	XCR Diagnostics
Venetec International	Walk Vascular, LLC	Xemax Surgical Products, Inc.
Ventec Life Systems	Wallach Surgical Devices, Inc.	Xenco Medical, LLC
Ventrex, Inc.	Water Pik, Inc.	Xhale Assurance, Inc.
Veratex	Waters Medical Systems, LLC	X-Spine Systems, Inc.
Veritas Medical Innovations	WaveSense, Inc.	YMed, Inc.
Versah LLC	WAVi Co	Young Dental Mfg. Company
Vertex Industries, Inc. Torbai Division	Wayne Metal Products Inc.	Zassi Medical Evolutions Bowel Management System LLC
Vertis Neuroscience	Weck Surgical Systems	Zefon International
Vertos Medical, Inc.	Welch Allyn Tycos Instruments, Inc.	Zefon Medical Products
Vesocclude Medical, LLC	Welch Allyn, Inc.	Zeto Inc
Vestibular Research & Development dba Balanceback	Welch Allyn Monitoring	Zevex International
Vestibular Technologies, LLC	Welcon, Inc.	ZIEN Medical Technologies
Vestil Manufacturing Innovation in Motion	Weldenz America Inc.	Zimmer, Inc.
Vevazz, LLC	WellDoc, Inc.	Zimmer Biologics
VGI Medical LLC	Wells Johnson Company	Zimmer Dental
VH Technologies Ltd.	Wellsky Corporation	Zimmer Orthopaedic Implant Div.
Viasys Healthcare, Inc. Bird Products Medical Data Electronics Nicolet Biomedical Sensormedics Corp.	West Pharmaceutical Services	Zimmer Orthopaedic Surgical Products
Vidamed, Inc.	Western systems Research Inc.	Zimmer Spine
Viewlight, LLC	Wexler Surgical, Inc.	Zimmer Tmt, Inc.
Viking Systems, Inc.	Whatman, Inc.	Zirc Dental Products, Inc.
ViOptix Inc.	Balston, Inc.	ZYTO Technologies
Vios Medical, Inc.	Balston, Ltd.	
Viral Control Technology, Inc.	PCI Scientific Supply	
Vision Sciences, Inc.	Whatman Far East PTE Ltd.	
	Whatman Int'l. Ltd.	
	Whatman K K	
	Whatman Lab Sales	
	Whatman Scientific, Ltd.	
	Wheaton Industries	
	Whip Mix Corporation	
	White Mountain Imaging	



HIBCC Clarification on LIC Fees



This statement is being released to respond to several inquiries concerning the cost to acquire Labeler Identification Code (LIC) assignments for labeling and UDI Implementation.

HIBCC is the accredited Secretariat and ANSI-Standards Development Organization for the HIBC Supplier Labeling Standard. We are also the designated FDA Issuing Agency for LIC assignments for HIBC-based Unique Device Identifiers (UDIs). It is our responsibility to assure the integrity of assigned LICs and establish equity in the cost to acquire LIC assignments.

HIBCC reaffirms its long-standing position that labelers are not required to pay continuing fees to acquire and maintain their LIC assignments. When HIBCC developed our Supplier Labeling Standard (SLS) in 1984 we established a one-time fee basis for assignment of the required Labeler Identification Code (LIC), i.e., the company prefix in the HIBC primary data structure (and more recently in the FDA required UDI). We have never waived from this position, which has been in place for over thirty years. Assigned LICs are permanent, never rescinded or reassigned, and globally deployable. Other than the initial one-time fee, LIC holders thereafter have no financial obligation to HIBCC.

Some HIBCC Labelers have previously registered for an LIC through HIBCC-affiliated organizations, and as a consequence may be paying recurring charges (or "dues"). This has led to some confusion. In order to assist those labelers, we are confirming that if they so choose they may elect to cease these payments and notify HIBCC so that we can update their contact information on our Global Labeler Database and continue to maintain their LIC on our registry. There is no charge associated with this update.

As has always been the case, any company seeking a new LIC that registers directly with HIBCC incurs no such recurring charges, regardless of the location of the applying company. The LIC assignment is global and there is no territorial exclusivity associated with the source of the assignment.

1. Unrecognized LIC Entered

Step One Enter Your Data

LIC is unrecognized. [Apply for an LIC.](#)

Labeler Identification Code	E700	Verify LIC	?
Product / Catalogue Number			
Unit of Measure / Package Indicator	0 ▼	?	

2. Correct LIC Entered

Step One Enter Your Data

The LIC registered address should match your FDA GUDID account information. If not, you can use our [Apply for or Update an LIC.](#)

Registered Company Name	IT CONCEPTS GMBH		
Division/Subsidiary Name			
Registered Company Address	GEWERBESTRASSE 17 LAHNAU HESSEN 35633 Germany		

Labeler Identification Code	B717	Verify LIC	?
Product / Catalogue Number			
Unit of Measure / Package Indicator	0 ▼	?	

Verizon

12:13 PM

25%

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Scanned Item

Close

UDI DEVICE IDENTIFIER

LIC

B718

Product/Catalog ID

1234

Unit of Measure

0

UDI DI

B71812340

UDI PRODUCTION IDENTIFIER

Lot Number

712991

Serial Number

N/A

Manufacture Date

N/A

Expiration Date

01/19

Quantity

N/A

UDI PI

0119712991



Call for applications in the view of the designation of UDI issuing entities in accordance with Article 27(2) of Regulation (EU) 2017/745 on medical devices (MDR) and Article 24(2) of Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR).

Form - Applicant's undertakings

Date: 23 January 2019

I, Kirk Kikirekov, in my quality of legal representative in the European Union of Prospitalia h-trak, Building 2, Walton Street, Ayelesbury HP21 7QW, United Kingdom confirm that Health Industry Business Communications Council intends to submit an application for being designated as an issuing entity in accordance with Article 27(2) of Regulation (EU) 2017/745 on medical devices (MDR) and Article 24(2) Regulation (EU) 2017/746 on *in-vitro* diagnostic medical devices (IVDR). In this context, Health Industry Business Communications Council, having read the conditions for designation as laid down in Section II of the call for application, undertakes to:

- (i) operate its system for the assignment of UDIs for at least ten years after its designation;
- (ii) make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;
- (iii) remain in compliance with the criteria for designation and the terms of designation

Date and signature of the applicant organisation's legal representative within the European Union

23 January 2019



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