IFA Coding System

Specification
Unique Device Identification (UDI)

Use of the IFA Coding System for medical devices
in accordance with Regulations (EU) 2017/745 and (EU) 2017/746

Supplement for manufacturers of medical devices

IFA
CODINGSYSTEM

Directory

1. Introduction

These specifications are a supplement to the IFA specifications PPN Code Specification for Retail Packaging[1] with the focus on the requirements that must be met when labelling medical devices in accordance with Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR). These specifications reference the respective chapter of the IFA specifications “PPN Code Specification for Retail Packaging” where appropriate.

The Informationsstelle für Arzneispezialitäten – IFA GmbH (IFA) is accredited as an issuing agency pursuant to ISO/IEC 15459-2 and facilitates use of the Pharmazentralnummer (PZN) and other number systems according to international standards with the so-called Pharmacy Product Number (PPN). The IFA Coding System is already successfully being used in the field of medicinal products during the implementation of the EU Falsified Medicines Directive. With COMMISSION IMPLEMENTING DECISION (EU) 2019/939 of 6 June 2019, the IFA was designated by the Commission as the issuing entity for UDI. As a result, the Coding System of the IFA is also available for labelling medical devices in accordance with the European Medical Device Regulation (MDR) and with the *In Vitro* Diagnostic Medical Devices Regulation (IVDR).

[1] https://www.ifaffm.de/mandanten/1/documents/04_ifa_coding_system/IFA_Spec_PPN_Code_Handelspackung_EN.pdf

2. Unique Device Identification (UDI) for medical devices

2.1. General

The Basic UDI-DI groups the products of a manufacturer that have certain identical properties (device models).

The product-specific UDI is composed of two parts, the Device Identifier (DI)[2] and the Production Identifier (PI)[3]. In accordance with the European labelling requirements, the UDI-DI serves to unambiguously identify a medical device. In addition to the Basic UDI-DI it is the main key for records in EUDAMED, the European database of medical devices. For the tracking of specific production series, the MDR provides the Production Identifier UDI-PI. The UDI-DI and the UDI-PI in principle must be affixed to the so-called UDI carrier for labelling in machine-readable format (AIDC) and in human readable format (HRI) on the product itself or its packaging as well as on the higher packaging levels. Shipping containers are not considered a higher packaging level.

The required data elements for labelling medical devices can be generated via the IFA Coding System. IFA provides those manufacturers who use the PZN for product identification with its Coding System and the PPN. No additional licencing costs are incurred.

The following sections provide a more detailed description of the UDI data elements and their generation. Details for the other data elements and their coding can be found in the IFA specifications PPN Code Specification for Retail Packaging[4]. In the examples in Chapter 5 as well as in Appendix A for lot number the term batch number is used as a term required by regulation on medicinal products.

2.2. Device Identifier – UDI-DI

For the use of the IFA Coding System, the PPN is used as the UDI-DI. The PPN represents the PZN with the prefix “11”[5] in an internationally unambiguous format:

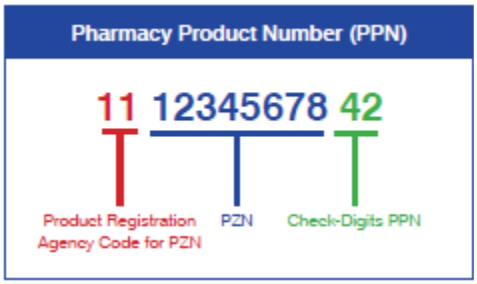

Figure 1: Structure of the PPN

[2] It should not be confused with the Data Identifier, which is also abbreviated as DI. To make a distinction, the device identifier is abbreviated as UDI-DI in this document.

[3] Abbreviated in this document analogously to the UDI-DI and in accordance with the MDR as UDI-PI.

[4] https://www.ifaffm.de/mandanten/1/documents/04_ifa_coding_system/IFA_Spec_PPN_Code_Handelspackung_EN.pdf

[5] With the Health Product Code (HPC), the IFA Coding System also includes item numbers assigned directly by the manufacturer. See "PPN Pharmacy Product Number - Technical Specification"

This PPN consists of three parts that are highlighted in red, blue and green. The “11” stands for a Product Registration Agency Code (PRA Code). This code is managed and assigned by IFA. The “11” is assigned to the German PZN. The national article number follows after the “11” and is represented in blue. This is the unmodified PZN (8 digits). The subsequent digits (shown in the figure in green) form the two-digit, calculated check number of the PPN across the entire data field (including the “11”). This together with the PZN represented in this example results in a value of “42”.

When issuing a PZN, IFA also issues this PPN directly at the same time or it can be generated via the PPN Generator[6].

In the Data Matrix Code (DMC), the PPN is represented with the data identifier “9N” (see Appendix A). During coding, the ASC data structure (Format 06) must be applied in accordance with subsection A in the IFA specifications PPN Code Specification for Retail Packaging Chapter 5.1, exactly as it corresponds to the requirement and application of the DELEGATED REGULATION (EU) 2016/161 OF THE COMMISSION of 2 October 2015 in conjunction with Directive 2011/62/EC (FMD – Falsified Medicines Directive).

2.3. Production Identifier – UDI-PI

Depending on the requirement for a medical device, the manufacturer determines the UDI-PI for his product and labels the packages accordingly. The UDI-PI can be the lot number (batch number), expiry date and, in certain cases, also the manufacturing date, a serial number assigned by the manufacturer or several of these data elements. This also applies to reusable medical devices that are to be refurbished. For these data elements, the data identifiers can be used pursuant to the international standard ANSI MH10.8.2. The details for the use of the common data elements are described in the IFA specifications PPN Code Specification for Retail Packaging in Chapter 5.2.2 and subsequent chapters. The compressed summary can be found in Appendix A of this specification.

2.4. Basic UDI-DI

The Basic UDI-DI is the main key for grouping those products of a manufacturer that have the same properties. According to the guideline “MDCG 2018-1 Guidance on BASIC UDI-DI and changes to UDI-DI”, these properties include the intended purpose, risk class, essential design and manufacturing characteristics. With the help of the Basic UDI-DI and via the databases, the joint reference to the products with regard to the documentation, specifically to the certificates, is to be created.

Since the Basic UDI is not meant to appear on the package, no data identifier is specified for this data element. For a standardised electronic exchange in XML format, the XML tag “B_UDI_DI” was specified for the Basic UDI-DI (see also Appendix A).

6 https://www.ifaffm.de/en/ifa-codingsystem/pzn-to-ppn/ppn-generator.html

The Basic UDI-DI is generated[7] from these four elements (substring elements):

- Issuing Agency Code (IAC)
- Manufacturer Code
- Device Group Code
- Check Digit

For the use of the IFA Coding System, the Basic UDI-DI is specified as follows:

Basic UDI-DI				
Substring element:	**IAC**	**Manufacturer Code**	**Device Group Code**	**Check Digits**
generated by:	IFA	IFA	Manufacturer	Modulo 97
Data type:	A	A/Num[8]	A/Num	Num
Character set:[9]	PP	0 – 9	0 – 9; A – Z; "."	0 – 9
Character length:	2	5	1 … 16	2
String length:	10 ... 25			
Example:	PP	12345	ABCD.12345678.90	04

Figure 2: Structure of the Basic UDI-DI

From the example shown in the table and from the sequence of the four elements (without additional delimiters) results the Basic UDI-DI: "**PP12345ABCD.12345678.9004**".

Supplementary information:

IAC: The code "PP" must always be used as the IAC assigned to IFA as the issuing agency.

Manufacturer Code[10]: Here, the manufacturer uses the five-digit IFA supplier number assigned by IFA. It can be found in the overview of supplier address data, which can be requested from IFA.

Device Group Code: This code for the product group in question is assigned by the manufacturer in consideration of the rules stipulated by the Commission. At the time these specifications were generated, the guideline "MDCG 2018-1 Guidance on BASIC UDI-DI and changes to UDI-DI" applied.

For any division within the substring "Device Group Code", the period "." can be used.

Check Digits: The check digits in two-digit format are formed via the first three substrings. Here, the method in accordance with Modulo 97 is used in identical form, as for the calculation of the check digits of the PPN. The procedure is described in the IFA document Technical Information – Check Digit Calculations[11].

The Basic UDI-DI is the main key in EUDAMED and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) to

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7 In accordance with Guidance MDCG 2019-1 MDCG Guiding Principles for Issuing Entities Rules on Basic UDI-DI.

8 At present, exclusively numeric manufacturer codes are assigned.

9 Corresponding ASCII characters: 48 – 57 for digits 0 – 9; 65 – 90 for characters A – Z; 46 for the "period".

10 Designated CIN (Company Identification Number) in the relevant standards.

11 https://www.ifaffm.de/mandanten/1/documents/04_ifa_coding_system/IFA-Info_Check_Digit_Calculations_PZN_PPN_UDI_EN.pdf

connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.

2.5. Data content and requirements for the Data Matrix Code (DMC)

For the data content and requirements for coding in the Data Matrix Code (DMC), the IFA specifications PPN Code Specification for Retail Packaging Chapters 6.1 to 6.4 apply.

2.6. Additional data elements

Also for this application, additional elements apart from the UDI data elements can be issued in the DMC. Examples are provided in Appendix A.

2.7. Additional article designations

If necessary, the manufacturer can incorporate additional article designations in the DMC that have emerged for specific markets. The unambiguous nature of the UDI-DI per se results from the PPN with the data identifier “9N”.

Examples can be found in Chapters 5.3.3 and 5.4 of the IFA specifications PPN Code Specification for Retail Packaging.

3. Marking with code and plain text format

3.1. Coding

The details of the symbology, useable matrix sizes and code dimensions including quiet zones are described in the IFA specifications PPN Code Specification for Retail Packaging Chapters 6.1 to 6.3.

There are no specific rules concerning code positioning. The manufacturer determines the position based on the package layout and the printing conditions, so that the AIDC is accessible during normal operations or normal storage.

3.2. UDI-Labelling in plain text format

3.2.1. General information

In principle, the MDR requires that the product is labelled with the UDI in machine-readable format (AIDC format) and in human readable format (HRI format).

All elements of the UDI have to appear on the label in the HRI format. In accordance with requests in appendix VI part C Section 4.8 MDR, IFA determines the HRI formats in this specification. IFA takes into account the manufacturer's varying needs in terms of their products, markets and established labelling.

In the following chapters, IFA specifies three formats from which the manufacturer can choose according to his circumstances. The manufacturer must take all aspects into account, including those to be considered in addition to the MDR.

In cases in which the MDR allows reductions with regard to placing AIDC- and HRI on the label (see Chapter 3.2.5), the following applies:

For articles that are to be labelled with the PZN pursuant to the framework agreement according to § 131 SGB V, the machine readability of the PZN is mandatory. The PZN must be issued either in Code 39 or in the Data Matrix Code (DMC) as a machine-readable PPN.

In addition, the framework agreement requires the PZN to be represented in a Human Readable Interpretation (plain text format)[12].

To ensure readability, the explications of the so-called EU Readability Guideline must be followed.[13]

3.2.2. HRI format "Symbol"

In this format, symbols or abbreviations commonly used at international level precede the corresponding UDI data as HRI qualifiers (identifiers). The UDI-DI is highlighted by means of a short identifier. This

[12] Either PZN in plain text format with the prefixed data identifying label "PZN: " or for usage of the PZN in Code 39 additionally in the obligatory plain text line.

[13] Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use.

very compact HRI representation is offered to manufacturers for applications in which solely the requirements of the MDR have to be considered.

For the elements of the UDI the following applies:

UDI-DI:

The UDI-DI is to be affixed with a short identifier: “UDI-DI (PPN): “. The term in brackets indicates that a PPN is being used. Example:

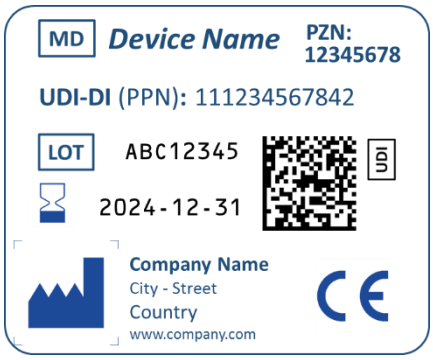
UDI-DI (PPN): 111234567842

UDI-PI:

All elements of the UDI-PI must appear on the label in HRI format. UDI-PI data must be prefixed with symbols or alternatively the short identifiers resulting from the legal regulations or from the manufacturer’s QM system. The layout is to be configured in a way the user can match the data inevitably. Short identifier consisting of data strings must be separated from data with a colon and spaces.

For usage of date specifications YYYY-MM-DD or YYYY-MM must be used unless legal provisions or the manufacturer’s QM system ask for a different format.

Example:



For more examples see Chapter 5.

Figure 3: Example HRI-Format “Symbol”

3.2.3. HRI format “Symbol +”

This format is based on the "Symbol" format described in the previous chapter. The only difference is that the identifier used in the code is added to the symbols.

This format is particularly suitable for certain exeptions defined according to legal obligations stipulating the representation of the UDI on the label in AIDC format can be omitted plus the UDI is placed on the label in HRI format exclusively (Requirement for machine readability of the PZN see Chapter 3.2.1).

Examples:

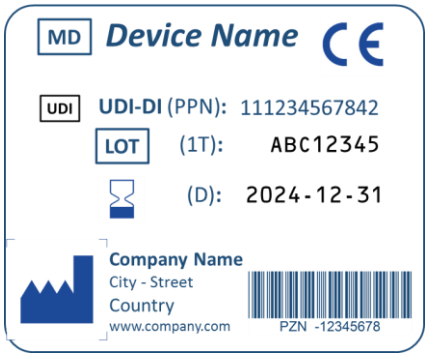


Figure 4: Example with PZN in Code 39

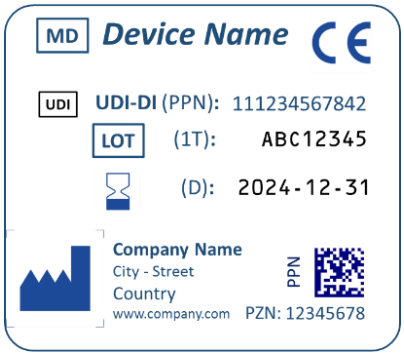


Figure 5: Example with PZN (PPN) in Data Matrix Code

The following table shows the indentifiers to be assigned to the corresponding data elements:

UDI Element	Data element[14]	Data identifying label[15]	Examples
UDI-DI	<PPN>	UDI-DI (PPN):	111234567842
UDI-PI	<LOT>	(1T):	1234AB
UDI-PI	<EXP>	(D):	2024-10-31
UDI-PI	<MFD>	(16D):	2019-08-31
UDI-PI	<SN>	(S):	12345678AB

Figure 6: Identifier for the HRI format “Symbol +”

For plain text representation, as many line breaks as necessary may be used, as long as interpretation is conclusive for the user.

3.2.4. HRI format “Interpretation Line”

The HRI format "interpretation line" provides for the output of the data fields with the corresponding data identifiers in exactly the same way as they are represented in the code. To delimit the data fields, the data identifiers used are to be placed in round brackets "()".

In addition to the interpretation line, the other information on the label resulting from the relevant legal regulations and the manufacturer's QM system must be added together with qualifiers commonly used at international level.

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14 Listed accordingly to the XML-node.

15 Attention must be drawn to the colon “: “ after the closing bracket of the short identifier.

This format conforms with the representations in the IMDRF UDI System Application Guide[16] and is suitable for cases in which the manufacturer has to consider these formats as well.

Example:

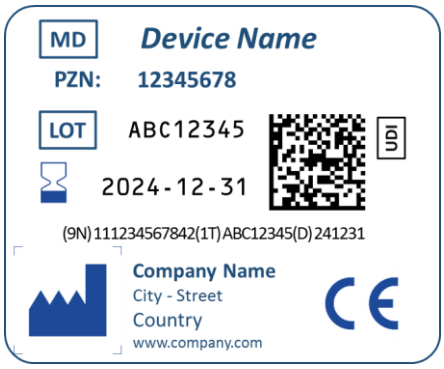


Figure 7: Example HRI-Format "Interpretation Line"

Furthermore, the interpretation line, like the "Symbol +" format described above, is suitable for the special constellations in which the MDR allows dispensing the representation of the UDI in AIDC format (code).

Requirements for machine readability and representation of the PZN in plain text format see Chapter 3.2.1.

3.2.5. Peculiarities

If there are significant constraints limiting the use of both formats – AIDC and HRI – on the labelling, the MDR allows in accordance to appendix VI part C section 4.7 to refrain from using the UDI in HRI format and simply use the AIDC format (code). But for products being generally used outside of healthcare facilities the HRI format is to be used primarily. Even though this may lead to no more available space for the AIDC format.

If the UDI is represented exclusively in HRI format, the format "Symbol +" according to Chapter 3.2.3 or "interpretation line" according to Chapter 3.2.4 must be applied. Examples see Figure 4 and Figure 5.

The special dispense with AIDC or HRI markings permitted under the MDR cannot be transferred to the requirements of the framework agreement according to § 131 SGB V for machine readability and representation of the PZN in plain text format (see Chapter 3.2.1).

3.3. HRI-Format for documentation and records

In addition to the HRI representation on the packages, there is the necessity to provide the UDI in documents.

For the correct interpretation of the data fields and contents, two formats are defined for the representation:

[16] International Medical Device Regulators Forum Unique Device Identification system Application Guide

- Output in XML-Format or
- Output in Format of the Data Identifiers

The XML format is preferred. It offers the advantage of universal representation and further processing, is detached from the specific machine language used in the code and is therefore commonly understood.

3.3.1. XML-Format

When choosing the XML format, XML nodes as defined in Appendix A and other commonly used data field identifiers shall be used. The data contents are provided as output as stored in the code. This means that the data formats according to Appendix A must be observed for the date specifications.

The data string is structured according to XML standards. Thus, hierarchical representation is also possible.

Example 1 – XML-Format (without hierarchy):

```
<PPN>111234567842<LOT>A1234<MFD>20200826
```

Example 2 – XML-Format in hierarchical structure:

```
<UDI>
    <UDI_DI>
        <PPN>11234567842
    </UDI_DI>
    <UDI_PI>
        <LOT>A1234
        <MFD>20200826
    </UDI_PI>
</UDI>
```

3.3.2. Data Identifier Format

In this format, the Data Identifiers and data contents are represented as they are contained in the code. For distinction the data identifiers are indicated in round brackets. The data contents are identical to the XML format (see above).

Example:

```
(9N)111234567842(1T)A1234(16D)20200826
```

3.4. Emblem for the Data Matrix Code (DMC)

If the space and printing techniques allow, it is recommended to affix the “UDI: ” emblem as a reference to the UDI carrier near the DMC. In doing so, the spacing (quiet zone) to the code must be observed.

4. Manufacturer Information in EUDAMED

The manufacturer is in accordance with Article 28 MDR required to register certain data elements, as elaborated in the document "MDR-UDI and device data sets to provide in EUDAMED" in the European database for medical devices (EUDAMED).

The relevant product keys are the UDI-DI as described in Chapter 2.2 and the Basic UDI-DI, generated by the manufacturer according to the specification in Chapter 2.4.

To identify IFA as Issuing Entity, the identifier "IFA" shall be selected for the information provided to EUDAMED.

The information can be registered in EUDAMED as soon as the UDI module is available. The Commission provides information on its EUDAMED website for details and timetable of the implementation.

5. Examples of UDI labelling on medical devices

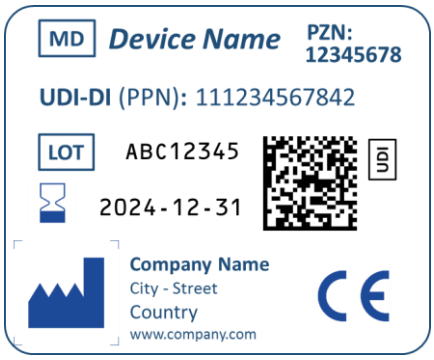
The following examples show different labelling versions of a UDI carrier. The tables represent the data fields with the data identifiers for coding in the Data Matrix Code (DMC). The associated labels bear the code, the HRI and other exemplary plain text.

5.1. Example 1 – Batch-related medical device

UDI-DI:
PPN (9N), example with the German PZN “12345678”

UDI-PI:
Batch number (1T) “ABC12345”
Expiry date (D) “31/12/2024”

Format	DI	Data
ASC	9N	111234567842
ASC	1T	ABC12345
ASC	D	241231



5.2. Example 2 – Medical device with PZN in Code 39

UDI-DI:
PPN (9N), example with the German PZN “12345678”

UDI-PI:
Batch number (1T) “ABC12345”
Expiry date (D) “31/12/2024”

Additional representation of the PZN in Code 39 on the label.

Format	DI	Data
ASC	9N	111234567842
ASC	1T	ABC12345
ASC	D	241231

5.3. Example 3 – Medical device with URL in the DMC

UDI-DI:
PPN (9N), example with the German PZN “12345678”

UDI-PI:
Expiry date (D) „31/12/2024“

Additionally, a URL (33L) is rendered in the DMC.

Format	DI	Data
ASC	9N	111234567842
ASC	D	240600
ASC	33L	http://ifaffm.de

5.4. Example 4 – Serialised medical device

UDI-DI:
PPN (9N), example with the German PZN “12345678”

UDI-PI:
Serial number (S) „JXCC263D0889“
Batch number (1T) “170400XYZ”
Expiry date (D) “17/06/2023”

Format	DI	Data
ASC	9N	111234567842
ASC	S	JXCC263D0889
ASC	1T	170400XYZ
ASC	D	230617

5.5. Example 5 – UDI-PI exclusively on the higher packaging level

Higher packaging level (outer packaging):

UDI-DI:
PPN (9N), example with German
PZN „12345678“

UDI-PI:
Manufacturing Date (16D) “25.07.2019”

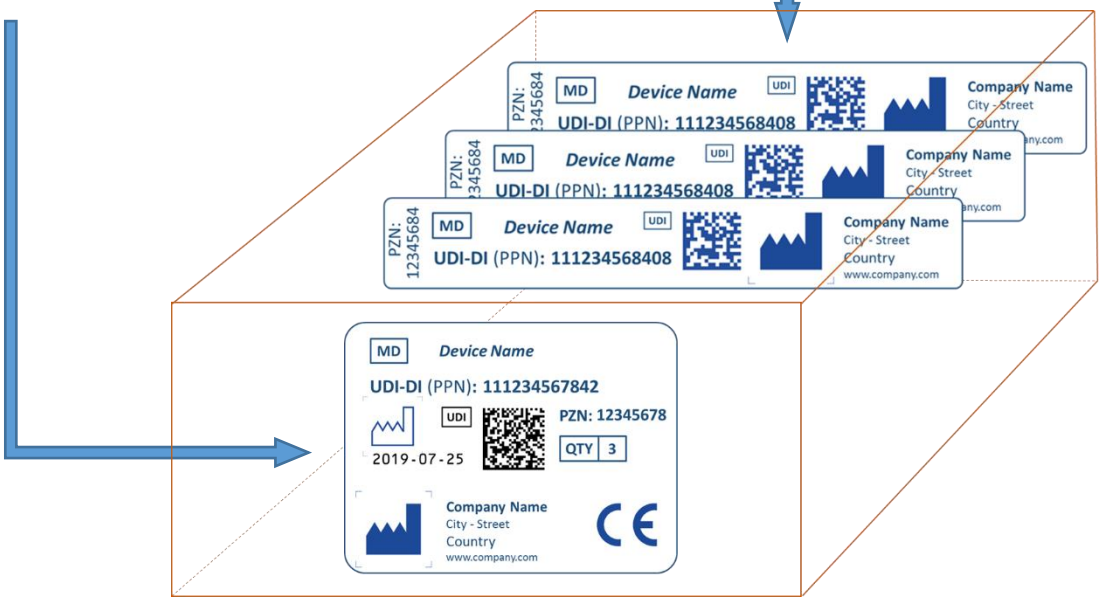
Additionally, the quantity (Q)
of the retail packs included in the higher packaging level is rendered in the DMC.

Format	DI	Data
ASC	9N	111234567842
ASC	16D	20190725
ASC	Q	3

Retail package:

UDI-DI:
PPN (9N), example with German
PZN „12345684“

Format	DI	Data
ASC	9N	111234568408



The PZN of the higher packaging level must be different from that of the retail package!

Appendix A: Overview and reference of the data identifiers

The table below specifies the characteristics of the individual data identifiers including the assigned XML nodes:

Data elements	XML Nodes	DI	Data type	Data format	Character length	Character set
Pharmacy Product Number (PPN)	<PPN>	9N	AN	—	4 – 22	0 – 9; A – Z no special characters, no use of lowercase letters, no national characters
Serial number	<SN>	S	AN	—	1 – 20	Numeric or alphanumeric characters, no national characters
Batch number	<LOT>	1T	AN	—	1 – 20	Numeric or alphanumeric characters, no national characters
Expiry date	<EXP>	D	Date	YYMMDD	6	0 – 9
Date of production	<MFD>	16D	N	YYYYMMDD	8	0 – 9
Quantity	<QTY>	Q	N	—	1 – 8	0 – 9
Price	<PRICE>	27Q	AN	0.00	1 – 20	0 – 9; “.” as decimal point
Basic UDI-DI	<B_UDI_DI>	--	AN	—	10 – 25	see Chapter 2.4
Hyperlink	<URL>	33L	AN	—		
National Trade Item Number (NTIN)	<GTIN>	8P	N	—	14	0 – 9

Note:

Details for the data elements can be found in the IFA specifications PPN Code Specification for Retail Packaging. It describes e.g. the applied character lengths and the format specifics of the expiry date.

Recommendations for the character set for serial number and batch number:

a) The character string should only include either uppercase or lowercase letters of the Latin alphabet.

b) To avoid human reading errors and depending on the font used and print quality, similar characters that are prone to be mistaken for each other should not be used. These include e.g.: i, j, l, o, q, u and I, J, L, O, Q, U.

c) While some special characters are technically processed[17], they should not be used because the risk of misinterpretation is very high. A misinterpreted code results in a package being unable to be identified.

d) If delimiters are necessary within a batch number, the use of a hyphen "-" or underscore "_" or period "."[18] is ecommended.

[17] The special characters with the decimal ASCII code values of 35 (#), 36 ($), 64 (@), 91 ([), 92 (\), 93 (]), 94 (^), 96 (`), 123 ({), 124(|), 125 (}), 126 (~) and 127 (¦) and all control characters (ASCII code value 00 – 31) are excluded from technical processing. In principle, all ASCII characters with a decimal value of more than 127 are excluded. The technically allowable characters are in accordance with "GS1 AI encodable character set 82" (GS1 General Specifications, section 7.11 (Figure 7/11-1)).

[18] The use of the period character is particularly recommended, since its location is identical in German and English keyboards. If the wrong language is selected for the keyboard scanners used, the risk of misinterpretation therefore does not exist per se.

Appendix B: Dokument history

Version	Date	Change log	Document action
1.0	1 July 2019	Initial Release	
1.02	11 July 2019	Layout-/Text correction	Appendix A: Corrections / errata
1.03	2 September 2019	Layout-/Text correction / content	Chap. 1: Text modified Chap. 3.2: Additions HRI-Representation Chap. 4: Examples modified
1.03a	23 October 2019	Layout-/Text correction	Chap. 4.5: errta corrected
1.04	1 July 2020	Layout-/ Text correction / content	Chap. 2.2: Addition HPC Chap. 2.4: Addition to Basic UDI-DI Chap. 3.2: HRI-Format extended Chap. 3.3: HRI-Format for Dokumentation new Chap. 4: Manufacturer Info EUDAMED new Chap. 5.5: Example modifed

IFA CODINGSYSTEM

For additional information on IFA GmbH, the IFA Coding System, the PZN and PPN, the UDI and technical specifications, please visit www.ifaffm.de or contact ifa@ifaffm.de.

The content was created with the greatest care. If you detect errors or are missing content, it is requested that you notify IFA.

The respective laws and regulations are legally binding.

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