

(disponible en français)

| 1. | NAME(S) OF DEVICE | LICENO | CE(S) BEING AMENDED | | | | |
|--------|-------------------------------------|-------------|---|---------------|-------------------|--------------|-------------------------|
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| 2. | LICENCE NUMBER(S | 5) TO BE | AMENDED: (provide the later | st valid lice | nce number(s)) | | |
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| 3. | MANUFACTURER IN act Name and Title: | FORMA' | TION (as it appears on the labe | el) | Company ID (if | Irnoven): | |
| | pany Name: | | | | Company ID (II | KIIOWII). | |
| _ | hone: | | Fax: | | E-mail: | | |
| Street | | | - w | | Suite: | | PO Box: |
| | | | | | | | |
| City: | I | Province/S | State: | Count | ry: | Po | stal/Zip Code: |
| 4. | DECLII ATODV CODI | PESDONI | DENT INFORMATION | □ Same as | Manufacturer □ | Other (speci | ify halow) |
| | act Name and Title: | CESI OIVI | DENT INFORMATION | □ Same as | Company ID (if | | ny ociow) |
| | oany Name: | | | | 1 7 | , | |
| Telep | hone: | | Fax: | | E-mail: | | |
| Street | t: | | | | Suite: | | PO Box: |
| City: | T _T | Province/S | State: | Count | rv. | Po | stal/Zip Code: |
| City. | 1 | TO VIIICE/E | ruic. | Count | i y . | 10 | omi zip coue. |
| 5. | INVOICING INFORM | ATION | ☐ Same as Manufacturer | ☐ Same a | s Regulatory Corr | | ☐ Other (specify below) |
| | act Name and Title: | | | | Company ID (if | known): | |
| | bany Name: | | Fax: | | E-mail: | | |
| Street | hone: | | rax. | | Suite: | | PO Box: |
| Street | | | | | Suite. | | TO BOX. |
| City: | I | Province/S | State: | Count | ry: | Po | stal/Zip Code: |
| | | | | | | | |
| 6. | ty Management System Cer | | STEM CERTIFICATE (ensurumber: | | ne of Registrar: | | |
| Quan | ty Management System Cer | illicate iv | umoer. | Ivaii | ic of Registrar. | | |
| 7. | ATTESTATIONS | | | | | | |
| | | | lical Devices Regulations relevations ontains the following attestation | | | | |
| | | | e Manufacturer of this device | | | | |
| | quality. | | | | | | <u> </u> |



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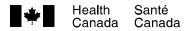
| | clare that these i | dentified statements are | | ication, hereby attest that I have direct knowledge of the iter d that the information provided in this application and in a | | | | |
|--|--|----------------------------------|--|---|------------|--|--|--|
| behalf. I further authors of this application. | Where a person is named in Item 4 of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Bureau to direct all correspondence relating to this application to the person named in Item 4 of this application. Please ensure that all information and documents set out in Section 32 of the <i>Medical Devices Regulations</i> that are relevant to the change has been enclosed. | | | | | | | |
| Name: | | Т | itle: _ | | | | | |
| | | | | | | | | |
| Signature: | | Г | Date: | | | | | |
| COMPLETE ITEMS 8 | and 9 ONLY IF | THEY HAVE CHANGE | ED FR | OM THE PREVIOUS LICENCE | | | | |
| 8. PLACE OF U | | | 3D 110 | | | | | |
| Is this device sold for | □ Yes | Is this device used at a p | point of | f care, such as a pharmacy, bedside, or healthcare | □ Yes | | | |
| home use? | □ No | professional's office? (I | n Vitro | Diagnostic Devices [IVDD] ONLY) | □ No | | | |
| Is this device an IVDD? | □ Yes | | | | | | | |
| 9. MEDICAL DI | EVICES CONTA | INING DRUGS | | | | | | |
| | IVD Devices Con | | | | | | | |
| If the device contains a d | Irug and is not an | IVDD_indicate the Drug I | dentific | eation Number (DIN) or the Natural Product Number (NPN) and | d complete | | | |
| the information listed be | low. If the drug d | | | se provide the Drug Establishment Licence (DEL) number of th | | | | |
| from where the drug is so | | | | DIMAIDM. | | | | |
| Brand / Trade Name of | Drug: | | | DIN/NPN: | | | | |
| Active Ingredient(s): | | | | | | | | |
| Drug Manufacturer: DEL Number: | | | | | | | | |
| DEL Nullibel. | | | | | | | | |
| 9.2 IVDI | D Test Kits conta | ining Controlled Substar | nces | | | | | |
| If this device is an IVDE section below. | test kit containin | g a substance listed in Sch | edule I | , II, III, or IV of the Controlled Drugs and Substances Act, com | plete the | | | |
| Is this an IVDD Test K | it containing a cor | ntrolled substance? | | Yes □ No | | | | |
| Test Kit Number (T.K. | | | | · | | | | |
| Please note: The manufa | acturer will need to | o contact the Office of Con | ntrolled | Substances to obtain a T.K. Number if one has not yet been iss | ued. | | | |
| 10. REASON FOI | R AMENDMENT | 「 (✓ appropriate change) | | | | | | |
| ► A change to | the classification | of the device | | From Class: To Class: | | | | |
| ► A change in | the Manufacturer | 's name | | Ensure that Item 1 is completed | | | | |
| A change in the device licence name (that is [i.e.] previous device name no longer available for sale) | | | New device licence name:(add attachment if more space is needed) | | | | | |
| A significant change in manufacturing process, facility of equipment | | | | | | | | |
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| • | A significant change in manufacturing quality control procedures | |
|---|---|--|
| • | A significant change in design or performance specifications | |
| • | A significant change in the materials | Device contains ≥ 0.1% w/w of Di (2-Ethyl hexyl) Pthalate [DEHP]* □ Yes □ No Device is manufactured from materials □ Yes □ No containing or derived from bisphenol A (BPA)* |
| • | A significant change in the labelling of the device | |
| • | Any change which could affect the safety and effectiveness of the device | |
| • | An addition, deletion or change in device components or associated model, part or catalogue numbers | Complete below |

^{*} Please consult the document "Guidance for Industry: How to Complete the Application for a New Medical Device Licence", which is available on the website, for the definition of DEHP and BPA.



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ADDITIONS (Before completing this section, please consult the document "Guidance for Industry: How to Complete the Application for a New Medical Device Licence", which is available on the website, for the definition of DEHP and BPA)

| Name of device, components, parts and/or accessories as per product label | Identifier for device (bar code, catalogue, model or part number) | DEHP | BPA | Preferred Name Code (FOR HEALTH CANADA USE ONLY) |
|---|---|------|-----|--|
| | | | | 37.21) |
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| For Therapeutic Directorate Use | |
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| Device Licence Application No. | |

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11B. DELETIONS

| Name of device, components, parts and/or accessories as per product label | Identifier for device (bar code, | Device ID Number |
|---|----------------------------------|------------------|
| | catalogue, model or part number) | |
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11C. CHANGES

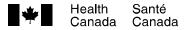
| IIC. CHANGES | + | | i |
|---|---|---|------------------|
| Name of device, components, parts and/or accessories as per product label | Old Identifier for device (bar code, catalogue, model or part number) | New Identifier for device (bar code, catalogue, model or part number) | Device ID Number |
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| 12. | COMPATIBILITY OF INTERDEPENDENT D IV device, provide a list of all medical devices that number. See <i>Notice to Industry – Licensing Require</i> complete list of licensed medical devices, refer to: v | this device is intended to be ments of Interdependent M | medical device intended to be used with another used or function with, including their medic | eal device licence |
|----------|---|---|--|--------------------|
| Name | of compatible device | , | Licence Num | ber |
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| 13. | LIST OF RECOGNIZED STANDARDS COMP (please answer "Yes" to one, and only one, of the fo | | ANUFACTURE OF THE DEVICE | |
| | nedical devices subject to this application conform wit inition and Use of Standards under the Medical Device | h Recognized Standards as | | □ Yes □ No |
| If yes | I am including with this application Declarations of O | Conformity that the medical | al device(s) comply with the following Recogn | nized Standards: |
| The n | nedical devices subject to this application DO NOT co | nform with Recognized St | andards but meet an equivalent or better | □ Yes |
| standa | * ** | momi with recognized St | andulus but meet an equivalent of better | □ No |
| If yes | I am including detailed information proving that the | device(s) meet the following | ng equivalent or better standards: | |
| | | | | Lev |
| | nedical devices subject to this application DO NOT co standard, but I am including detailed information as e | | | □ Yes □ No |
| 14. | FEES | | | |
| Please i | ndicate that the Medical Device Licence Application Fee | Form has been included w | ith this application form \square | |
| Class I | II Amendment Form (June 2016) | -7- | For Therapeutic Directorate Use | |

Device Licence Application No. ___



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LICENCE APPLICATION DISCLOSURE REQUEST

As you are aware, Health Canada is striving to add transparency to the medical device review process. One area we would like to address is the requests from interested parties regarding whether or not a licence application has been received by the Medical Devices Bureau (MDB).

The purpose of this form is to request your signed authorization - in advance - if we receive such a request, to disclose the date on which a licence application has been received by the MDB. No other information would be supplied.

Please indicate your consent by completing this form and sending it with your application for a new medical device licence, or any time after a licence has been granted.

| nce, or any time after a licence has been granted. |
|---|
| elosure Statement: |
| ne case where the Medical Devices Bureau (MDB) has received requests concerning the status of the new licence ication, amendment application, or fax-back application for (enter device name) |
| n interested parties, |
| this certifies that (enter the manufacturer's name) |
| has no objection to the disclosure to the requester, by the MDB, of the date when an application for the device entered above, has been received by the MDB |
| this certifies that (enter the manufacturer's name) |
| objects to the disclosure to the requester, by the MDB, of the date when an application for the device entered above, has been received by the MDB |
| ccordance with the <i>Access to Information Act</i> , confidential, third party information will not be disclosed without expressed consent. |
| Manufacturer's authorized signing official |
| lication forms should be sent to: |
| Device Licensing Services Division |
| Medical Devices Bureau |

Phone: (613) 957-7285 Facsimile: (613) 957-6345

Health Canada 11 Holland Avenue Address Locator: 3002A OTTAWA, Ontario K1A 0K9

E-mail: device licensing@hc-sc.gc.ca

Therapeutic Products Directorate