



E-Manufacturer's Certificate to Export Licensed Medical Devices from Canada-Certificate of Free Sale (FRM-0539)

We, the undersigned manufacturer of the following devices:

| Part 1 – I | | | | | | | | | |
|---|----------------------------------|------------------------------------|-------------------------------------|-------------------------------|--------------------------|---|-------------------------|-------------|--|
| , | | | | | nd the MDL i | nformation for your Class II, III a | and IV medical devices) | | |
| | | | | cence (MDEL) | | | | | |
| MDEL # (Class I medical devices): | | | Device(s) name: | | | | | | |
| Medical | DeviceL | icence | (MDL) | | | | | | |
| MDL #: | | | MDL Class # | t: Device | Device(s) name: | | | | |
| Interim C | Order (IC |) autho | rizations | , | | | | | |
| IO author ID#: | rization | Device | (s) name: | | | IO authorization date: (yyyy-mm-dd) Device identifier #: | | | |
| b) to | each dev Food and ests hav | ice is ma I Drugs i e been d | A <i>ct</i> and the conducted fo | Medical Device or each device | e Regulati and the te | anada in accordance with ions thereunder ests indicate that the natu ormance characteristics o | re of the benefits cla | aimed to be | |
| Part 2 - Name and address of manufacturer | | | | | | | | | |
| Company | / ID (6 di | gits): | Name: | | | | | | |
| Street ad | dress: | | | | | | | | |
| City: | | Р | Province: | | | Postal code: | | | |
| Part 3 – | Signatu | re of au | thorized pe | erson (print na | me and t | itle of the authorized pe | rson) | | |
| Name: | | | | | | Signature: | | | |



| MDL# | Device identifier | MDL Class # | Device(s) name |
|------|--------------------------|---------------|-----------------|
| IDL# | (model/catalogue detail) | (II, III, IV) | Device(s) fiame |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

Version 1 2023/01/18

For Office Use Only



Health Canada

Regulatory Operations and Enforcement Branch

It is hereby certified that:

- a. Devices manufactured, produced and sold in the manner above described would not, by reason of the method of manufacture thereof, be in violation of the Act and the Regulations thereunder
- b. Devices manufactured and sold in compliance with the Act and the Regulations may be exported without restriction

| Devices li | sted are regis | stered and | sold in Can | ada and are of free s |
|------------|----------------|------------|-------------|-----------------------|
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Medical Devices Establishment Licence Unit Medical Devices and Clinical Compliance Directorate Regulatory Operations and Enforcement Branch Health Canada

Disclaimer: This certificate is valid only if signed by Health Canada with all pages included. The validity of the signature can only be viewed electronically.

Privacy Notice

The personal information you provide to Health Canada will be used by the Regulatory Operations and Enforcement Branch under the *Food and Drug Act* and the *Medical Devices Regulations* and handled in accordance with the *Privacy Act*.

Why are we collecting your personal information? We require your personal information, including your name, title and manufacturer information to process your request for a Manufacturer's Certificate to Export Licensed Medical Devices from Canada.

Will we use or share your personal information for any other reason? We may also share your personal information with Global Affairs Canada to authenticate the certificate.

What happens if you don't want to provide your personal information? Failure to provide the requested information may prevent the processing of your request for a Manufacturer's Certificate to Export Licensed Medical Devices from Canada.

What are your rights? You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights or about how we handle your personal information, please contact us by email at mce.questions-cfe@hc-sc.gc.ca.

Version 1 2023/01/18