Health Canada Santé Canada

Protected B When Completed

FRM-0451: Delegation of mandatory shortage and discontinuation reporting for medical devices, pursuant to the *Medical Devices Regulations*

When to use this form

This form authorizes the organization named in **Section B** (importer) below to act on behalf of the organization named in **Section A** (manufacturer) in regard to **mandatory shortage reporting** for an anticipated or actual medical device shortage and a **medical device discontinuation** and to act as the Canadian Regulatory Contact for medical device shortage reporting.

Please note that the manufacturer can authorize one importer to report mandatory shortages and/or medical device discontinuations on its behalf.

How to complete this form

Section A of this form should be completed by the manufacturer. By completing the form, the manufacturer confirms that they authorize the importer to report any mandatory shortage (anticipated or actual) or discontinuation of medical devices and to provide any required information and/or documentation.

Section B of this form should be completed by the importer. By completing this form, the importer confirms that they will be reporting any shortage (anticipated or actual) or discontinuation of medical devices and will provide any required information and/or documentation, on behalf of the manufacturer.

How to submit your form

The completed form should be sent to Health Canada at MD.shortages.Penurie.de.IM@hc-sc.gc.ca.

Manufacturers must provide, in writing, any amendments/modifications for their authorization letter to the above-mentioned coordinates.

Section A: Manufacturer

I hereby authorize the organization named in **Section B, on my behalf,** to prepare and submit information and/or documents with respect to **mandatory shortage reporting and medical device discontinuations,** as defined in the *Medical Devices Regulations*.

Company name:			
Address:			
City:	Province/State:	Country:	Postal/Zip code:
Phone:	Fax:		
Email:			
Name of authorized representative:	Title:		
Signature:	Date (yyyy-mm-dd):		

Canada

Section B: Importer		
I hereby accept the designation as the Canadian Regulatory Contact for **mandatory shortage reporting and medical device discontinuation reporting and** accept that Health Canada may contact our organization on behalf of the organization named in **Section A**.		
Company name:		
Address:		
City:	Province:	Postal code:
Phone:	Fax:	
Email:		
Name of authorized representative:	Title:	
Signature:	Date (yyyy-mm-dd):	