Revision History

Revision	Change Order Number	Description of Change
1A	CO10258688	DC1047 HMS Plus System, DC1055 HMS Cartridges, DC1079 HMS Controls have been obsoleted. These DoCs have been consolidated (previously assigned to TF-0047) and align with new TF-0167 number. Reference to the Essential Requirements Checklist has been updated to reference 10678811DOC.
AA	RCH00016440	Update ISO 13485 Certificate number to Q5 039709 1211 Rev. 00 and standard from 2012 to 2016

Attachments

Attachment ID	Title
Attachment A	Declaration of Conformity DC1167
Attachment B	Declaration of Conformity DC1167 Applicable Standards

EC Declaration of Conformity

Manufacturer:	Medtronic Inc. 710 Medtronic Parkway N.E. Minneapolis, MN 55432 United States of America
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Manufacturing Facility	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA Medtronic Parker Blood Management 18501 East Plaza Drive, SS-66 Parker, CO 80134 USA
Product:	**Attachment A**
Classification, Rules:	IVDD Class "Other" not included in Annex II, List A or B, not for self-testing
Conformity Assessment Route	Annex III (excluding section 6)

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 98/79/EC of 27 October 1998 including amendments issued and ISO 13485:2012, which apply to them. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied:	See **Attachment B**
Quality System Certificate:	Q5 039709 1211 Rev. 00
EC Design Examination Certificate:	Not Applicable
Place of Issue:	Minneapolis, Minnesota USA

Authorized Signature:

Name: Jake Roeller
Title: Senior Manager, Regulatory Affairs
Date: 03-May-2019

Attachment A: Declaration of Conformity DC1167

This attachment specifies the IVDD Class "Other" products included in the above referenced Declaration of Conformity.

A.) HMS Plus

Device Description	Model Number	Variant(s)
HMS Plus Instrument	30514	NA
HMS Plus Instrument	30515	NA
HMS Plus Instrument	30517	NA
HMS Plus Instrument	30518	NA
HMS Plus Instrument	30522	NA
HMS Plus Instrument	30524	NA
HMS Plus Instrument	30526	NA
HMS Plus Instrument	30527	NA
HMS Plus Instrument	30528	NA
HMS Plus Barcode Scanner	HMSPLUSSC	NA
HMS Plus Barcode Scanner	HMSPLUSSCRS	NA
HMS Plus Barcode Scanner	HMSPLUSSCYY	NA
HMS Plus External Data Manager	HMSPLUSEDM	NA
HEPtrac Electronic Quality Control	313-51	NA

B.) Heparin Dose Response (HDR) Cartridge

Device Description	Model Number	Variant(s)
Heparin Dose Response Cartridge	304-20POR	NA

C.) Heparin Assay Cartridges (HPT-4 and 6 Channel)

Device Description	Model Number	Variant(s)
Heparin Assay Cartridges	304-01POR	NA
Heparin Assay Cartridges	304-02POR	NA
Heparin Assay Cartridges	304-03POR	NA
Heparin Assay Cartridges	304-04POR	NA
Heparin Assay Cartridges	304-05POR	NA
Heparin Assay Cartridges	304-06POR	NA
Heparin Assay Cartridges	304-07POR	NA
Heparin Assay Cartridges	304-08POR	NA
Heparin Assay Cartridges	304-09POR	NA
Heparin Assay Cartridges	304-10POR	NA
Heparin Assay Cartridges	304-11POR	NA

D.) High Range Activated Clotting Time (HR-ACT)

Device Description	Model Number	Variant(s)
High Range Activated Clotting Time Cartridge	304-30	NA

E.) Heparin Assay Controls

Device Description	Model Number	Variant(s)
Heparin Assay Controls	306-01POR	NA
Heparin Assay Controls	306-02POR	NA
Heparin Assay Controls	306-03POR	NA
Heparin Assay Controls	306-04POR	NA
Heparin Assay Controls	306-05POR	NA
Heparin Assay Controls	306-09POR	NA

Attachment B: Declaration of Conformity DC1167 Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned on the applicable CE Mark certificate.

Standard Number	Description
EN ISO 13485:2016	Medical Devices – Quality management systems – Requirements for regulatory purposes.

For product specific standards refer to 10678811DOC for the product.