Rev	CO#	Description of Change
1A	CO10260821	DC1065 ACT Plus has been obsoleted. This new DoC has been created (previously assigned to TF-0065) to align with new TF-0166 number Update header, footer and format to current document template 11025 Update reference to Essential Requirements Checklist to reference 10678816DOC Update 710 Medtronic Parkway address to 710 Medtronic Parkway N.E.
AA	RCH00016990	Update ISO 13485 Certificate number to Q5 039709 121 Rev. 00
AB	RCH00241399	Remove certificate Q5 039709 1211 Rev. 00 as it is not required for IVD. Remove ISO13485:2016 standard reference from body of the document. Add new Manager signature

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.
This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied: See **Attachment B**

Place of Issue: Minneapolis, Minnesota USA

Authorized Signature: Kristyn M. Benson

Name: Kristyn Benson
Title: Sr. Director, Regulatory Affairs
Date: 25 Mar 2022

Attachment A to Declaration of Conformity DC1166

This attachment specifies the class "Other" not included in Annex II List A or B and not for self-testing In Vitro Diagnostic Devices included in the above referenced Declaration of Conformity.

A.) ACT Plus

Device Description	Model Number	Variant(s)
ACT Plus	ACT100	NA
ACT Plus	ACT200	NA
ACT Plus	ACT2000BV	NA
ACT Plus	ACT20001	NA
ACT Plus	ACT20002	NA
ACT Plus	ACT20003	NA
ACT Plus	ACT20004	NA
ACT Plus	ACT20005	NA
ACT Plus	ACT20006	NA
ACT Plus	ACT20008	NA
ACT Plus	ACT20024	NA
ACT Plus	ACT20041	NA
ACT Plus	ACT20046	NA
ACT Plus – reconditioned unit	RACT200	NA
ACT Plus External Data Manager	ACTEDM	NA
ACT Plus Barcode Scanner	ACTSC	ACTSCC4 ACTSC66

B.) Activated Clotting Time (ACT) Cartridges

Device Description	Model Number	Variant(s)
Low Range Activated Clotting Time Cartridge	402-01	NA
Recalcified Activated Clotting Time Cartridge	402-02	NA
High Range Activated Clotting Time Cartridge	402-03	NA
High Range ACT Easy Fill Device	ACTFLHR	NA
Low Range ACT Easy Fill Device	ACTFILLR	NA

C.) Heparinase Test Cartridge (HR-HTC)

Device Description	Model Number	Variant(s)
Heparinase Test Cartridge	402-07	NA

D.) HR Normal and Abnormal Controls

Device Description	Model Number	Variant(s)
CLOTtrac HR Normal Coagulation Control	550-07	NA
CLOTtrac HR Abnormal Coagulation Control	550-08	NA
CLOTtrac HR Coagulation Control Pack	550-13	NA

E.) CWB Control

Device Description	Model Number	Variant(s)
CLOTtrac CWB Control	550-01	NA

F.) LR Abnormal Control and Calcium Chloride

Device Description	Model Number	Variant(s)
CLOTtrac LR Abnormal Coagulation Control	550-09	NA
Calcium Chloride	550-11	NA

G.) RACT Abnormal Control

Device Description	Model Number	Variant(s)
CLOTtrac RACT Abnormal Coagulation Control	550-10	NA

H.) HTC Control

Device Description	Model Number	Variant(s)
CLOTtrac HTC Coagulation Control	550-12	NA

Attachment B to the Declaration of Conformity DC1166: Applicable Standards

The below mentioned Standards apply to all the product(s) mentioned this Declaration of Conformity

Standard	Description
EN ISO 13485: 2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

For product specific standards refer to the 10678816DOC for the product.