Rev	CO#	Description of Change
1E	CO10218985	Update to G1 QS Certificate Update font to Effra Update Branding and Trademark where appropriate Update header and footer to match Technical File template Update Authorized Signature
1F	CO10270569	Update to Attachment A to align with the devices listed in the corresponding technical file Update Attachment B with the 13485:2016 ISO Standard
AA	RCH00058744	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update template and minor formatting changes

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 United States of America
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands
Product:	**Attachment A**
Classification, Rules:	Class IIa, Rule 3 (Uncoated models)
Conformity Assessment Route	Annex II excluding section 4

I, the undersigned, hereby declare that the Medical Devices specified above and provided with the CE marking, meet the provisions of Council Directive 93/42/EEC of 14 June 1993 as amended by 2007/47/EC which apply to them. This declaration is supported by the Certificates according to the provisions of relevant Annex of above Directive. This declaration applies to all devices specified above distributed from the signature date forward.

Standards Applied:	See **Attachment B**
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstr 65 D-80339 München, Germany
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1263 REV. 00
Place of Issue:	Minneapolis, Minnesota USA
Authorized Signature:	 Name: Jake Roeller Title: Senior Manager, Regulatory Affairs Date: 19-Feb-2020

Attachment A to Declaration of Conformity DC1135

This attachment specifies the products included in the above referenced Declaration of Conformity.

A.) AutoLog Auto-transfusion Disposables

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Autotransfusion System, Centrifuge Bowl	ATL2001	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL400)	ATLS00	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL402)	ATLS02	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL404)	ATLS04	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001,BT715,EL404)	ATLS14	NA	3	G1 039709 1263 REV. 00
Autolog One Source Pack (ATL2001, BT725, EL2120)	ATLS21	NA	3	G1 039709 1263 REV. 00
One Source Pack	ATLS24	NA	3	G1 039709 1263 REV. 00
Special holding bag 1000 ml	BT1000SC	NA	3	G1 039709 1263 REV. 00
Autotransfusion Centrifuge Bowl 125ml	BT125E	NA	3	G1 039709 1263 REV. 00
ELMD Vacuum ext line with 4 ft	BT133	NA	3	G1 039709 1263 REV. 00
Vacuum ext line with filter	BT133F	NA	3	G1 039709 1263 REV. 00
Autotransfusion Centrifuge Bowl, 225ml	BT225E	NA	3	G1 039709 1263 REV. 00
Suction/Anticoagulation line 15 ft	BT715	NA	3	G1 039709 1263 REV. 00
Suction/Anticoagulation assembly	BT725	NA	3	G1 039709 1263 REV. 00
Tandem cardiotomy "Y" adaptor	BT920	NA	3	G1 039709 1263 REV. 00
Reservoir "Y" adaptor with ¼" outlets	BT926	NA	3	G1 039709 1263 REV. 00
Straight stepdown 3/8"-1/4" connector	BT946	NA	3	G1 039709 1263 REV. 00
Suction/Anticoagulant Line including "Y" Adapter with ¼" outlets	BTC93	NA	3	G1 039709 1263 REV. 00
Suction & Anticoagulant line with stepdown 3/8" – ¼" adaptor	BTC96	NA	3	G1 039709 1263 REV. 00

Device Description	Model Number	Variant(s)	MDD Rule	QS Certificate
Transfer spike	BT945	NA	3	G1 039709 1263 REV. 00
Plasma Sequestration kit for blood bags	BT727SP	NA	3	G1 039709 1263 REV. 00
Waste Bag, Universal 10 liter	ELUWB1	NA	3	G1 039709 1263 REV. 00
Blood Processing One-Source Packs	STANDBY1	NA	3	G1 039709 1263 REV. 00
Blood processing kit w/125 ml bowl	TK1	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S00	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S02	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S04	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S21	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK1S24	NA	3	G1 039709 1263 REV. 00
Blood Processing Kit w/225 ml bowl	TK2	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S00	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S02	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S04	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S21	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S24	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S2469	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood processing	TK2S247	NA	3	G1 039709 1263 REV. 00
One Source Pack, Blood Processing	TKSP	NA	3	G1 039709 1263 REV. 00

Attachment B to the Declaration of Conformity DC1135: Applicable Standards

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

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

For product specific standards refer to the Essential Requirements Checklist for the product.