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Medtronic CORONARY AND STRUCTURAL HEART	Number DC2004	Revision AE	Page 1 of 6
Title: Declaration of Conformity: Arterial Blood Filters, Non-Sterile Bulk			

Rev	CO#	Description of Change
1A	CO10088672	Introduce new EU Declaration of Conformity for Non-sterile Bulk Carmeda-coated AF100 Arterial Filter
1B	CO10168281	Update G1 and G7 Carmeda certificates Add Cortiva branded product names and certificates Update Document title to align with newly issued certificates Update Medtronic Address to add "N.E." Add Design Facility and Manufacturing Facility Update to Notified Body address. Added Header to all pages Update font to Effra.
AA	RCH00016440	Update ISO 13485 standard from 2012 to 2016 Update the header to match Technical file template Update footer information Update authorized signee Added non-sterile model M932313A001 and applicable certificate
AB	RCH00043111	Addition of non-sterile Uncoated and Balance Bonded Arterial Filters to DC2004. Added Classification/Rules, Conformity assessment route, EC Quality System Certificate for the uncoated and Balance coated models. Updated Cortiva references. Removed reference to G7 15 12 39709 01038 (Carmeda Coated Products)
AC	RCH00061981	Update EC Quality System Certificate from G1 16 08 39709 01060 to G1 039709 1263 Rev. 00 Update the manufacturer address Update the template and minor formatting changes
AD	RCH00068530	Minor formatting changes Addition of new EC Certificate G7 039709 1310 Rev.00 for the Cortiva Coated Non-Sterile Arterial Filters. Addition of new G1 Certificate for Cortiva G1 039709 1318 Rev. 00. Addition of new G1 Certificate for Uncoated and Balance coated devices G1 039709 1304 Rev. 00
AE	RCH00122102	Updated Authorized signature

Digitally signed by Kojevnikov Dmitrii
Date: 2024.09.17 15:56:03 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EC DECLARATION OF CONFORMITY

Manufacturer:	Medtronic, Inc. 710 Medtronic Parkway Minneapolis, MN 55432 USA
EC Representative	Medtronic B.V. Earl Bakkenstraat 10 6422 PJ Heerlen THE NETHERLANDS
Design Facility	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA
Manufacturing Facility	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 USA Medtronic Mexico S.de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. Tijuana, Baja California, MEXICO
Product:	**Attachment A**
Classification, Rules:	Class IIa, Rule 3 (Uncoated models) Class IIa, Rule 3 (Balance coated models) Class III, Rule 3, 13, 17 (Carmeda/ Cortiva coated models)
Conformity Assessment Route	Annex II.3 (for Class IIa) Annex II.3 combined with II.4 (for Class III)

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[1] 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.

Note: The components listed in this Declaration of Conformity are not finished devices. These components are only provided in non-sterile bulk form to the procedure pack manufacturer for further assembly into cardiopulmonary bypass perfusion circuits. These components are not intended to be sold directly to an end user.

Standards Applied:	See **Attachment B**
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65 80339 München GERMANY
Identification Number:	0123
EC Quality System Certificate:	G1 039709 1318 Rev. 00 (Carmeda/Cortiva Coated Products) G1 039709 1304 REV. 00 (Uncoated and Balance Bonded Products)
EC Design Examination Certificate(s):	G7 039709 1310 Rev.00 (Cortiva Coated Products)
Place of Issue:	Minneapolis, Minnesota USA
Authorized Signature:	

Name: Heather Taylor
Title: Senior Regulatory Affairs Manager
Date: 17 FEB 2021

[1] *Including amendments issued in the years following*

Attachment A to Declaration of Conformity DC2004

This attachment specifies the products included in the above referenced Declaration of Conformity. The following is an outline of the list of products presented in each section of this attachment:

Non-Sterile Bulk Affinity™ AF100 Arterial Filter (Cortiva Coated)
Non-Sterile Bulk Affinity Pixie™ Arterial Filter (Cortiva Coated)
Non-Sterile Bulk Affinity™ Arterial Blood Filter (Uncoated)
Non-Sterile Bulk Affinity™ Pediatric Arterial Filter (Uncoated and Balance Bonded)
Non-Sterile Bulk Affinity™ AF100 Arterial Filter (Balance Bonded)

Affinity™ AF100 Arterial Filter (Cortiva Coated)

Device Description	Model Number	CFN	Variant(s)	MDD Rule	EC Certificate
Non-Sterile Affinity™ AF100 Arterial Filter with Carmeda® BioActive Surface for inclusion into procedure packs Non-Sterile Affinity™ AF100 Arterial Filter with Cortiva™ BioActive Surface for inclusion into procedure packs	CB851	M944212A001	NA	Rule 3, 13, 17	G7 039709 1310 (Cortiva)

Affinity Pixie™ Arterial Filter (Cortiva Coated)

Device Description	Model Number	CFN	Variant(s)	MDD Rule	EC Certificate
Non-Sterile Affinity Pixie™ Arterial Filter with Cortiva™ Bioactive Surface for inclusion into procedure packs	CB4014	M932313A001	NA	Rule 3, 13, 17	G7 039709 1310 (Cortiva)

Affinity™ Arterial Blood Filter (Uncoated)

Device Description	Model Number	CFN	Variant(s)	MDD Rule	EC Certificate
Non-Sterile AFFINITY® 20µ Arterial Blood Filter for inclusion into procedure packs	353	61399409511	NA	Rule 3	G1 039709 1304
Non-Sterile AFFINITY® 38µ Arterial Blood Filter for inclusion into procedure packs	351	61399401125	NA	Rule 3	G1 039709 1304

Non-Sterile Bulk Affinity™ Pediatric Arterial Filter (Uncoated and Balance Bonded)

Device Description	Model Number	CFN	Variant(s)	MDD Rule	EC Certificate
Non-Sterile AFFINITY® Pediatric Arterial Filter for inclusion into procedure packs	S4014	M929334A001	NA	Rule 3	G1 039709 1304
Non-Sterile AFFINITY® Pediatric Arterial Filter with Balance Biosurface for inclusion into procedure packs	BB4014	M942233A001	NA	Rule 3	G1 039709 1304

Non-Sterile Bulk Affinity™ AF100 Arterial Filter (Balance Bonded)

Device Description	Model Number	CFN	Variant(s)	MDD Rule	EC Certificate
Non-Sterile AFFINITY® AF100 Arterial Filter with Balance Biosurface for inclusion into procedure packs	BB851	M944213A001	NA	Rule 3	G1 039709 1304

Attachment B to the Declaration of Conformity DC2004: 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 in TF-0004 and WKG-1010.