

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 1 din 01.10.2023

Solicitantul Oxivit Med SRL, cu sediul mun.Chisinau, MD-2020, Stradela Studentilor, 6b, tel./fax: +37368781333, e-mail oxivit.medical@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

- 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)

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 01/10/2023

Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: Oxivit Med SRL, cu sediul mun.Chisinau, MD-2020, Stradela Studentilor, 6b,

declar pe proprie răspundere, cunoscând prevederile art. **352¹**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

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

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Semnătura _____

Kojevnikov Dmitrii, director

Data 01/10/2023

TO WHOM IT MAY CONCERN

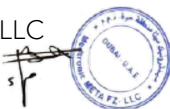
Date: 29.05.2023

We hereby certify that, pursuant to a non-exclusive distribution agreement expiring on 31 May 2024 between **Medtronic META FZ-LLC** (the "Company"), a Medtronic company organized under the laws of the United Arab Emirates having its principal place of business at 3rd Floor, Injaz Building, Dubai Knowledge Park, Dubai, United Arab Emirates, and **OXIVIT-MED, SRL**, a company having its principal place of business at Bld. Moscova 14/1., Chisinau, MD-2068, Republic of Moldova, the latter is authorized to act as the Company's distributor in Republic of Moldova for the below listed product lines:

- Cardiac Ablation Solutions;
- Cardiac Rhythm Management.
- Cardiovascular Diagnostics & Services;
- Cardiac Surgery
- Coronary & Renal Denervation
- Structural Heart & Aortic
- Peripheral & Endovenous
- Cranial & Spinal Technologies
- Neuromodulation
- Pelvic Health
- Ear, Nose & Throat
- Neurovascular
- Surgical Innovation
- Gastrointestinal
- Patient Monitoring
- Respiratory interventions
- Diabetes

This letter is valid until 31 May 2024 and can also be used with the Competent Authorities in Moldova for notification of medical devices manufactured by attached Medtronic and Covidien Legal Manufacturers, or other regulatory purposes.

Medtronic META FZ-LLC

M. N. ALANI 

Name: Muzahim Al Ani

Title: Authorized Signatory

APPENDIX 1

Medtronic Manufacturing Facilities/Legal Manufacturers:

1. Medtronic, Inc., 710 Medtronic Parkway, Minneapolis MN 55432, USA
2. Medtronic, Inc., 7000 Central Avenue N.E., Minneapolis MN 55432, USA
3. Medtronic, Inc., 3800 Annapolis Lane, Minneapolis MN 55447, USA
4. Medtronic, Inc., 8200 Coral Sea Street N.E., Mounds View, MN 5512, USA
5. Medtronic Europe Sàrl, Route du Molliau 31, Case Postale, CH-1131 Tolochenaz, Switzerland
6. Medtronic Bakken Research Center B.V., Endepolsdomein 5, 6229 GW Maastricht, The Netherlands
7. Medtronic CoreValve LLC, 1851 E. Deere Avenue, Santa Ana, CA 92705, USA
8. Medtronic MiniMed, 18000 Devonshire street, Northridge CA 91325-1219, USA
9. Medtronic Heart Valves Division, 1851 East Deere Avenue, Santa Ana, CA 92705, USA
10. Medtronic Heart Valves, 1941 Blair Avenue, Santa Ana CA 92705, USA
11. Medtronic Fabrication S.A.S. Zone Industrielle SUD, Route D'Anor, 59610 Fourmies, France
12. Medtronic Sofamor Danek USA, Inc., 1800 Pyramid Place, Memphis, TN 38132, USA
13. Medtronic Sofamor Danek USA, Inc., 4340 Swinnea Road, Memphis TN 38118, USA
14. Medtronic Sofamor Danek Manufacturing, 2500 Silveus Crossing, Warsaw IN 46582, USA
15. Medtronic Sofamor Danek Deggendorf GmbH, Werfstrasse 17, 94469 Deggendorf, Germany
16. Medtronic Sofamor Danek Deggendorf GmbH, Ulrichsberger Str. 17, 94469 Degendorf, Germany
17. Medtronic Xomed, Inc. 6743 Southpoint Drive North, Jacksonville FL 32216, USA
18. Medtronic Xomed Instrumentation S.A.S., Le Pavillon, Saint Aubin Le Monial, 03160 Bourbon-L'Archambault, France
19. Medtronic Xomed, Inc., 950 Flanders Road, Mystic CT 06355, USA
20. Medtronic Xomed, Inc., 80 Davids Drive # 5, Hauppauge, NY 11788, USA
21. Medtronic Powered Surgical Solutions, 4620 North Beach Street, Forth Worth, Texas 76137, USA
22. Medtronic Navigation, Inc. (Littleton), 300 Foster Street, Littleton, MA 01460, USA
23. Medtronic Navigation, Inc., 826 Coal Creek Circle, Louisville, CO 80027, USA
24. Medtronic Navigation Israel, Ltd. Kochav Yokneam Building, P.O.Box 548, 20692 Yokneam Elit, Israel
25. Kyphon Sàrl, Pierre-à-Bôt 97, 2000 Neuchâtel, Switzerland
26. AF Solutions, Medtronic Inc., 8200 Coral Sea Street, Mounds View, Minneapolis MN 55112, USA
27. Medtronic Ireland, Parkmore Business Park West Galway, Ireland
28. Medtronic Vascular, 35-37a Cherry Hill Drive, Danvers, MA 01923, USA
29. Medtronic Vascular, 3576 Unocal Place, Santa Rosa, CA 95403, USA
30. Medtronic Puerto Rico Operations Co., Juncos, Road 31, Km. 24, Hm 4, Ceiba Norte Industrial Park, Juncos PR 00777, USA
31. Medtronic Puerto Rico Operations Co., Villalba, Rd 149, Km 56.3, Call Box 6001, PR 00766 Villalba, USA
32. Medtronic Puerto Rico Operations, Co., Road 909 Km. 0.4 Bo, 00792 Barrio Mariana, Humacao, Puerto Rico, USA
33. Medtronic Puerto Rico Operations, Co., Parcela #21, Catano Industrial Park, Dr. John A. Smith Street, 00792 Humacao, Puerto Rico, USA
34. Medtronic Mexico S. de R.L. de CV, Av. Paseo Cucapah, 10510 El Lago, C.P. 22210 Tijuana, Baja California, Mexico
35. Medtronic Mexico EG, Carreta Internacional Guadalajara – Nogales, Empalme, Sonora, Mexico 85340
36. Medtronic Singapore Operations Pte. Ltd., 49 Changi South Avenue 2, Nasaco Tec Centre, 486056 Singapore
37. Medtronic Atrial Fibrillation Technologies (AFT), 8200 Coral Sea Street NE, Mounds View, Minneapolis MN 55112, USA
38. Medtronic Perfusion Systems, 7611 Northland Drive, Minneapolis, MN 55428, USA
39. Medtronic Perfusion Systems, 18501 East Plaza Drive, Parker CO 80134-9061, USA
40. Medtronic Cardiac Surgery Division Europe, Valkenhuizerlaan 16, 6466 ND Kerkrade, The Netherlands

41. Medtronic Neuromodulation, 800 53rd Avenue N.E., Minneapolis MN 55421, USA
42. Medtronic Neuromodulation, 7000 Central Avenue N.E. Minneapolis MN 55432, USA
43. Invatec S.p.A., 7, Via Martiri Della Libertà, 25030 Roncadelle, Brescia, ItalyInvatec S.p.A., 26-28 Via Industria, 25030 Torbole-Casaglia, Brescia, Italy
44. Medtronic Ardian LLC, 1380 Shorebird Way, Mountain View, CA 94043, USA
45. Medtronic Neurosurgery, 125 Cremona Drive, Goleta, CA 93117, USA
46. Medtronic Advanced Energy, LLC, 180 International Drive, Portsmouth NH 03801, USA
47. Vitatron Holding B.V. Endepolsdomein 5, 6229 GW Maastricht, The Netherlands
48. HeartWare, Inc.14400 NW 60th Avenue, Miami Lakes, Florida 33014, USA
49. BELLCO SOCIETÀ, Unipersonale A r.l., Via Camurana 1, 41037 Mirandola (MO), IT - Italy
50. Medtronic CryoCath LP., 9000 Autoroute Transcanadienne, Pointe Claire, Quebec H9R 5Z8, Canada
51. CardiolInsight Technologies Inc., 11000 Cedar Ave, Suite 210, Cleveland, OH 44106
52. Medtronic Vascular Inc., 271 Gibraltar Drive, Sunnyvale, CA 94089
53. Teleflex Medical, Annacotty Business Park, Annacotty, Co. Limerick, Ireland
54. TYRX Inc., 1 Deer Park Dr. Suite G Monmouth Junction, NJ 08852
55. HeartWare Inc., 500 Old Connecticut Path Framingham, MA 01701
56. Medtronic Sofamor Danek Inc., Airport Logistics Center, Building "A", 4340 Swinnea Road, Memphis, TN 38118, USA
57. Medtronic Monitoring Inc., 1410 Energy Park Dr. Saint Paul, MN 55108
58. Medtronic Vascular, 3850 Brickway Blvd, Santa Rosa, CA 95403 USA
59. Osteotech, Inc., 201 Industrial Way, Eatontown, New Jersey, 07724, USA
60. Medtronic Spine LLC, 1860 Barber Ln, Milpitas, CA 95035
61. Changzhou Kanghui Medical Inovation Co., Ltd., No. 11, North Chanjiang Road, Xinbei District, Changzhou 213022, P.R. China

List of EC Representatives:

1. Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands
2. Medtronic Ireland, Parkmore Business Park West, Galway, Irelandkang
3. Invatec S.p.A., 7, Via Martiri Della Libertà, 25030 Roncadelle, Brescia, Italy

List of Medtronic Distribution Centers:

1. Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands
2. Medtronic, Inc. Mounds View Distribution, 2292 Wooddale Dr, Ramsey, 55112 Mounds View, USA
3. Medtronic, Inc. Grand Rapids Distribution, 2925 Walkent Ct NW, Walker, MI 49544, USA
4. Medtronic, Inc. Blood Management Business, 18501 East Plaza Drive, Parker CO 80134-9061, USA
5. Medtronic, Inc. Western Distribution Center, 2385 Railroad Street, Corona, CA 92880, USA
6. Medtronic Xomed, Inc. Jacksonville Distribution, 6743 Southpoint Drive North, Jacksonville, FL 32216, USA
7. Xomed MicroFrance Distribution, Le Pavillon, Saint Aubin Le Monial, 03160 Bourbon-L'Archambault, France
8. Medtronic Sofamor Danek, Inc., Airport Logistics Center, Building "B", 4340 Swinnea Road, Memphis, TN 38118, USA
9. Medtronic Powered Surgical Solutions, 4620 North Beach Street, Forth Worth, Texas 76137, USA
10. Medtronic Leipzig Distribution 3PL, Dingolfinger Strasse 19, 04349 Leipzig, Germany
11. Puerto Rico Distribution Center, Santander Tower, B-7 Tabonuco Street, Suite 1501, Guaynabo PR 00968-3028, USA
12. Medtronic, Inc. New York Distribution Center East, Exel 3PL, 699 Kapkowski Road, Suite 300, Elizabeth NJ 07201-2122, USA
13. International Shipping Associate, UPS-SCS / Medtronic, 1860 Outerloop Road, Louisville, KY 40219, USA
14. Medtronic Navigation, Inc., 826 Coal Creek Circle, Louisville, CO 80027, USA
15. Medtronic Neurosurgery, 125 Cremona Drive, Goleta, CA 93117, USA
16. Swedesboro, NJ Distribution Center, 1130 Commerce Boulevard, Swedesboro NJ 08085
17. Guaynabo Distribution Center Sector La Muda Rd #1, Km 21.1, Guaynabo PR 00971, USA

18. MDT Logistics LLC DC East, 1130 Commerce Blvd Ste 100, Swedesboro, NJ 08085-1765 USA

Covidien Manufacturing Facilities/Legal Manufacturers, EC Representatives and Distribution Centers.

Covidien llc (USA)

- 15 Hampshire Street, Mansfield, MA 02048 USA
- 5439 State Route 40 Argyle, NY 12809 USA
- 1430 Marvin Griffin Road Augusta, GA 30906 USA
- 815 Tek Drive Crystal Lake, IL 60039 USA
- 525 North Emerald Road Greenwood, SC 29646 USA
- 1448 Blue Ridge Boulevard Seneca, SC 29672 USA
- 1313 West Grant Boulevard Wabasha, MN 55981USA
- Two Ludlow Park Drive Chicopee, MA 01022 USA
- 400 Maple Street Commerce, TX 75428 USA
- 2010 East International Speedway Boulevard Deland, FL 32724 USA
- 1222 Sherwood Road Norfolk, NE 68701USA
- 150 Glover Avenue, Norwalk, CT 06856 USA
- 60 Middletown Ave, North Haven, CT 06473 USA
- Building 911-67, Sabanetas Industrial Park, Ponce, Puerto Rico 00731
- At 101a Fist Avenue, Waltham, MA 02451, USA
- 5920 Longbow Dr., Boulder, CO 80301, USA
- 15 Crosby Drive, Bedford, MA 10730, USA
- 6135 Gunbarrel Ave., Boulder, CO 80301, USA
- 675 McDonnell Blvd., Saint Louis, MO 63134, USA
- formerly Barrx Medical Inc., 540 Oakmead Parkway Sunnyvale, CA 94085, USA

Covidien llc (Canada)

- Ludlow Technical products Canada Ltd., 215 Herbert Street Gananoque, Ontario K7G 2Y7 Canada
-

Covidien llc (Mexico)

- 37 Boulevard Insurgentes, Libramiento a la P, La Mesa Tijuana, B.C., Mexico
- Calle 9 Sur No. 125 Cuidad Industrial Tijuana, Mexico CP 22500
- Boulevard Insurgentes 19030 Libramiento, 22225 Tijuana, B.C., Mexico
- Avenue Henequen No. 1181, Parque Industrial Salvarcar, 32573 Ciudad Juarez, Chihuahua, Mexico

Covidien llc (Dominican Republic)

- Zona Franca de San Isidro, Carretera San Isidro Km 17 Santo Domingo, Dominican Republic

Covidien llc (Europe)

- Wilson Way Pool Industrial Estate Redruth, Cornwall TR15 3QN United Kingdom Unit 1, Astley Lane Industrial Estate Swillington Leeds West Yorkshire LS26 8XT, United Kingdom
- IDA Business and Tehcnology Park, Srah Industrial Estate Tullamore, Co. Offaly, Republic of Ireland
- Cornamaddy Athlone, Co. Westmeath, Ireland
- Michael Collins Road Mervue, Co. Galway, Ireland
- Via G. Bove, 2/4/6/8 Mirandola (MO) Italy 41037
- Quedlinburger Strasse 39A Halberstadt, D-38820 Germany

Covidien llc (Thailand)

117 Moo 2, Petchkasem Rd. Klongmai Sampran, Nakornpathom, 73110, Thailand

Covidien Ilc (Japan)

SBS Hills 1, 4-10-2 Yoga Setagaya-ku Tokyo 158-8615, Japan

Covidien Ilc Newton (Beacon)

2000 Commonwealth Avenue, 1st Floor, Newton, MA 0246, USA

Covidien AG

Victor Von Bruns-Strasse 19, 8212 Neuhausen am Rheinfall, Switzerland

Covidien Logistics BVBA

Weg naar Zwartberg 239, 3660 Opplabbeek, Belgium

Covidien Ireland Commercial Limited

3rd Floor, Kilmore House, Park Lane, Spencer Dock, Dublin 1

Covidien Medical Products (Shanghai) Manufacturing LLC

Bldg. 10, No. 789 Puxing Rd. Shanghai, P.R. China

Covidien (China) Medical Devices Technology Co., Ltd.

Floor 6, Building 3, #2388 Chenhong Road, 201114 Shanghai, P.R. China

Covidien Deutschland Manufacturing GmbH

Gewerbepark 1, 93333 Neustadt an der Donau, Germany

Covidien Manufacturing Solutions SA

Edificio B20 Calle #2 Zona Franca Coyol Alajuela, Costa Rica

Covidien, formerly known as Valleylab, A Division of Tyco Healthcare Group LP

5920 Longbow Drive Boulder, CO 80301 USA

Covidien, formerly Kendall-Gammatron Co. Ltd.

117 Moo 2, Petchkasem Rd. Klongmai Sampran, Nakornpathom, 73110, Thailand

Covidien, formerly MMJ S.A. de C.V.

Avenue Henequen No. 1181, Parque Industrial Salvarcar, 32573 Ciudad Juarez, Chihuahua, Mexico

EV3 Inc.

4600 Nathan Lane North Plymouth, MN 55442 USA

Micro Therapeutics Inc. d/b/a ev3 Neurovascular

9775 Toledo Way, Irvine, CA 92618 USA

superDimension Inc.

161 Cheshire Lane, Suite 100, Plymouth, Minnesota 55441, USA

Sofradim Production

116 Avenue du Formans, 01600 Trévoux, France

VNUS Medical Technologies, Inc.

5799 Fontanoso Way, San Jose CA 95138, USA

Given Imaging, Inc.

15 Hampshire Street, Mansfield MA 02048, USA

Given Imaging, Ltd

2 Hacarmel St. New Industrial Park POB 258 Yoqneam, Ha Zafon 20692 Israel

Given Imaging (Los Angeles) LLC

Los Angeles 5860 Uplander Way Culver City, CA 90230 USA

Given Imaging Vietnam Co. Ltd.

Suite 6A, 6th floor, Standard Factory Buliding, 14th Street, Tan Thuan EPZ, Tan Thuan Dong Ward, District 7, Ho Chi Minh City, Vietnam

Wem Equipamentos Eletrônicos Ltda.

Rua. Marechal Mascarenhas de Moraes 550, Parque Industrial Lagoinha, Ribeirão Preto, São Paulo - CEP 14095-120, Brazil

**List of OEM - Original Equipment Manufacturers
and Sub-Contracting Facilities:**

MindFrame, Inc.

12 Goodyear, Suite 125, Irvine, CA 92618, USA

Buffalo Filter, LLC

5900 Genesee St., Lancaster, NY 14086, USA

SCHÖLLY FIBEROPTIC GmbH

Robert-Bosch-Strasse 1-3, 79211 Denzlingen, Germany

W.O.M. World Of Medicine GmbH

Salzufer 8, 10587 Berlin, Germany

Liebel-Flarsheim Company Llc

2111 East Galbraith Road, Cincinnati, OH 45237 USA

Mediquip SDN. BHD.

- Padang Lati, Mukim Paya, P.O. Box 25, 01700 Kangar, Perlis, Malaysia
- Batu 5, Padang Lati, Jln. Santan, Kangar, 02450 Kangar, Perlis, Malaysia

Mallinckrodt Développement France S.A.S.

10 Allee Pelletier Doisy, 54601 Villers-Lès-Nancy, France

Mallinckrodt DAR S.R.L.

Via G. Bove, 2/4/6/8, Mirandola MO 41037, Italy

Mallinckrodt Medical

Cornamaddy Athlone, Co. Westmeath, Ireland

SOMANETICS CORP.

1653 East Maple Road, Troy, MI 48083-4208, USA

Aspect Medical Systems

1 Upland Road, Norwood MA 02062, USA

POLYSUTURE

Av.Gabriel Ramos da Silva, 1245 Pq.Industrial II, São Sebastiao. Paraíso, Minas Gerais, Cep: 37950-000 Brasil

 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

 Medtronic CORONARY AND STRUCTURAL HEART	Number DC2004	Revision AE	Page 2 of 6
Title: Declaration of Conformity: Arterial Blood Filters, Non-Sterile Bulk			

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)

 Medtronic CORONARY AND STRUCTURAL HEART	Number DC2004	Revision AE	Page 3 of 6
Title: Declaration of Conformity: Arterial Blood Filters, Non-Sterile Bulk			

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 1993¹ 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

 Medtronic CORONARY AND STRUCTURAL HEART	Number DC2004	Revision AE	Page 4 of 6
Title: Declaration of Conformity: Arterial Blood Filters, Non-Sterile Bulk			

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)

 Medtronic CORONARY AND STRUCTURAL HEART	Number DC2004	Revision AE	Page 5 of 6
Title: Declaration of Conformity: Arterial Blood Filters, Non-Sterile Bulk			

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

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

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.



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 039709 1304 Rev. 00

Manufacturer:

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies):

- Autotransfusion Systems and Associated Disposables
- Centrifugal Blood Pumps
- Bio-Console Drive Units
- Flow Monitoring Systems
- Bio-Cal Blood Temperature Controller
- Temperature Monitoring Systems and Associated Disposables
- Blood Monitoring Systems
- Cardioplegia Delivery Systems
- Disposable Blood Handling Devices used for Open Heart Surgery
- Arterial Filters
- Oxygenators including Heat Exchangers, with and without Cardiectomy Reservoirs
- Cardiotomy Venous Reservoirs
- Venous Reservoir Bags
- Perfusion Equipment and Disposable Perfusion Devices
- Disposable Medical Devices for Drainage Systems
- Disposable Medical Devices for use in Extracorporeal Support: Cardioplegia, Cannulae, Catheters, Venting, Suction
- Pressure Display System & related accessories of class IIa
- Tissue Positioning/Stabilizing Devices
- Surgical Site Clearing Devices
- Intravascular Shunts
- Surgical Retractors

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

72157211

Valid from:

2020-04-29

Valid until:

2024-05-26

Date,

2020-04-29

Christoph Dicks
Head of Certification/Notified Body