

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 4 din 29.09.2023

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:

- Cardiovascular PTCA Guidewires
- Cardiovascular Angiographic Guide Wires

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de împuternicire

Data 29/09/2023

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:

- Cardiovascular PTCA Guidewires
- Cardiovascular Angiographic Guide Wires

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Kojevnikov Dmitrii, director

Semnătura _____

Data 29/09/2023

TO WHOM IT MAY CONCERN

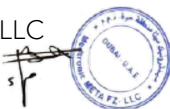
Date: 29.05.2023

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 and 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

Declaration of Conformity

DAN-DOC-006

Legal Manufacturer:	Medtronic Inc. 710 Medtronic Parkway N.E. Minneapolis, MN 55432 USA
EC Authorized Representative:	Medtronic Ireland Parkmore Business Park West Galway, Ireland
Design Facility:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923 USA
Manufacturing Facilities:	<u>PTCA Guidewires:</u> CEA Global Dominicana Zona Franca Industrial San Pedro de Macoris, Dominican Republic 21000 <u>Angiographic Guide Wires:</u> C.R. Bard 289 Bay Road Queensbury, NY 12804 USA
Product Families:	Guidewires Cardiovascular PTCA Guidewires and Cardiovascular Angiographic Guidewires
Products:	See attached product listing
Classification:	Class III, based on Annex IX, Rule 6 of Directive 93/42/EEC (MDD)

DAN-DOC-006

Notified Body: TÜV SÜD Product Service GmbH,
Identification No. 0123
Ridlerstrasse 65
Munich, Germany 80339

EC Quality Certificate: G1 039709 1357 Rev. 00
23/06/2020 (Date of Issue)
26/05/2024 (Date of Expiry)

EC Design Certificate: G7 039709 0970 Rev.01
01/01/2020 (Date of Issue)
26/05/2024 (Date of Expiry)

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD) including amendments issued, which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by a conformity assessment according to 93/42/EEC (MDD), Annex II.3 Approval as well as the EC Design Examination Certificate listed above.

Signed on behalf of the manufacturer exclusively responsible for the declaration of conformity:

Place: Medtronic Vascular Danvers Date: _____

Declaration of Conformity

Form

Medtronic

D00098623

Revision D

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Name: Nisarg Shah

Title Manager of Regulatory Affairs Signature: _____

Attachment 1

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

Standard Number	Description
EN ISO 13485: 2016	Quality Management Systems – Requirements for Regulatory Purposes

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

Declaration of Conformity

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Attachment 2

Product: Cardiovascular PTCA Guidewires

Model Number	Description
CGRLS190HJ	Cougar LS 0.014" 190cm J Hydrophilic
CGRLS190HS	Cougar LS 0.014" 190cm straight Hydrophilic
CGRLS300HS	Cougar LS 0.014" 300cm straight Hydrophilic
CGRXT190HJ	Cougar XT 0.014" 190cm J Hydrophilic
CGRXT190HS	Cougar XT 0.014" 190cm straight Hydrophilic
CGRXT300HJ	Cougar XT 0.014" 300cm J Hydrophilic
CGRXT300HS	Cougar XT 0.014" 300cm straight Hydrophilic
CGRLS300HJ	Cougar LS 0.014" 300cm J Hydrophilic
CGRXT190S	Cougar XT 0.014" 190cm straight Pro/Pel
CGRXT300S	Cougar XT 0.014" 300cm straight Pro/Pel
CGRXT190J	Cougar XT 0.014" 190cm J Pro/Pel
CGRXT300J	Cougar XT 0.014" 300cm J Pro/Pel
CGRLS190S	Cougar LS 0.014" 190cm straight Pro/Pel
CGRLS300S	Cougar LS 0.014" 300cm straight Pro/Pel
CGRLS190J	Cougar LS 0.014" 190cm J Pro/Pel
CGRLS300J	Cougar LS 0.014" 300cm J Pro/Pel
ZNGRLS180HJ	Zinger Light 180cm J Tip Hydrophilic
ZNGRLS180HS	Zinger Light 180cm Straight Tip Hydrophilic
ZNGRLS300HJ	Zinger Light 300cm J Tip Hydrophilic
ZNGRLS300HS	Zinger Light 300cm Straight Tip Hydrophilic
ZNGRMK180HJ	Zinger Marker 180cm J Tip Hydrophilic
ZNGRMK180HS	Zinger Marker 180cm Straight Tip Hydrophilic
ZNGRMK300HJ	Zinger Marker 300cm J Tip Hydrophilic
ZNGRMK300HS	Zinger Marker 300cm Straight Tip Hydrophilic
ZNGRMS180HJ	Zinger Medium 180cm J Tip Hydrophilic
ZNGRMS180HS	Zinger Medium 180cm Straight Tip Hydrophilic
ZNGRMS300HJ	Zinger Medium 300cm J Tip Hydrophilic
ZNGRMS300HS	Zinger Medium 300cm Straight Tip Hydrophilic
ZNGRS180HJ	Zinger Support 180cm J Tip Hydrophilic
ZNGRS180HS	Zinger Support 180cm Straight Tip Hydrophilic
ZNGRS300HJ	Zinger Support 300cm J Tip Hydrophilic
ZNGRS300HS	Zinger Support 300cm Straight Tip Hydrophilic
ZNGRLS180J	Zinger Light 180cm J Tip Pro/Pel
ZNGRLS180S	Zinger Light 180cm Straight Tip Pro/Pel
ZNGRLS300J	Zinger Light 300cm J Tip Pro/Pel
ZNGRLS300S	Zinger Light 300cm Straight Tip Pro/Pel

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FTDOP116978-13 Rev AC

Declaration of Conformity

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Model Number	Description
ZNGRMK180J	Zinger Marker 180cm J Tip Pro/Pel
ZNGRMK180S	Zinger Marker 180cm Straight Tip Pro/Pel
ZNGRMK300J	Zinger Marker 300cm J Tip Pro/Pel
ZNGRMK300S	Zinger Marker 300cm Straight Tip Pro/Pel
ZNGRMS180J	Zinger Medium 180cm J Tip Pro/Pel
ZNGRMS180S	Zinger Medium 180cm Straight Tip Pro/Pel
ZNGRMS300J	Zinger Medium 300cm J Tip Pro/Pel
ZNGRMS300S	Zinger Medium 300cm Straight Tip Pro/Pel
ZNGRS180J	Zinger Support 180cm J Tip Pro/Pel
ZNGRS180S	Zinger Support 180cm Straight Tip Pro/Pel
ZNGRS300J	Zinger Support 300cm J Tip Pro/Pel
ZNGRS300S	Zinger Support 300cm Straight Tip Pro/Pel
THNDR190S	THUNDER 190cm Straight Tip Pro/Pel
THNDR190J	THUNDER 190cm J Tip Pro/Pel
THNDR300S	THUNDER 300cm Straight Tip Pro/Pel
THNDR300J	THUNDER 300cm J Tip Pro/Pel
INTU180HS	Intuition, hydro coating, 180 cm, 5pk
INTU180SS	Intuition, silicone coating, 180 cm, 5pk
INTU300HS	Intuition, hydro coating, 300 cm, 5pk
INTU300SS	Intuition, silicone coating, 300 cm, 5pk
3PROV180HS	ProVia 3, hydro coating, 180 cm, 5pk
3PROV180SS	ProVia 3, silicone coating, 180 cm, 5pk
3PROV300HS	ProVia 3, hydro coating, 300 cm, 5pk
3PROV300SS	ProVia 3, silicone coating, 300 cm, 5pk
6PROV180HS	ProVia 6, hydro coating, 180 cm, 5pk
6PROV180SS	ProVia 6, silicone coating, 180 cm, 5pk
6PROV300HS	ProVia 6, hydro coating, 300 cm, 5pk
6PROV300SS	ProVia 6, silicone coating, 300 cm, 5pk
9PROV180HS	ProVia 9, hydro coating, 180 cm, 5pk
9PROV180SS	ProVia 9, silicone coating, 180 cm, 5pk
9PROV300HS	ProVia 9, hydro coating, 300 cm, 5pk
9PROV300SS	ProVia 9, silicone coating, 300 cm, 5pk
12PROV180HS	ProVia 12, hydro coating, 180 cm, 5pk
12PROV180SS	ProVia 12, silicone coating, 180 cm, 5pk
12PROV300HS	ProVia 12, hydro coating, 300 cm, 5pk
12PROV300SS	ProVia 12, silicone coating, 300 cm, 5pk
15PROV180HS	ProVia 15, hydro coating, 180 cm, 5pk
15PROV180SS	ProVia 15, silicone coating, 180 cm, 5pk
15PROV300HS	ProVia 15, hydro coating, 300 cm, 5pk
15PROV300SS	ProVia 15, silicone coating, 300 cm, 5pk

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FTDOP116978-13 Rev AC

Declaration of Conformity

Form

Medtronic

D00098623

Revision D

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Product: Cardiovasulcar Angiographic Guide Wires:

Model Number	Description
002501	PTFE coated guide wires .035" 145cm 3mm "J" fixed core
002502	PTFE coated guide wires .038" 145cm 3mm "J" fixed core
002503	PTFE coated guide wires .035" 145 cm straight fixed core
006200	SOS open ended GW .038" 145 cm straight standard taper core
006201	SOS open ended GW .038" 145 cm straight long taper core
006203	SOS open ended GW .035" 145 cm straight standard taper core
006204	SOS open ended GW .035" 145 cm straight long taper core
006210	Removable Luer Lock Hub SOS Wires
006305	Soft wire guide wires .035" 145cm straight PTFE coated fixed core
006307	Soft wire guide wires .038" 145cm straight PTFE coated fixed core
007041	PTFE coated guide wires .035" 120cm 3mm "J" fixed core
007042	PTFE coated guide wires .035" 145cm 3mm "J" fixed core
007043	PTFE coated guide wires .038" 120cm 3mm "J" fixed core
007044	PTFE coated guide wires .038" 145cm 3mm "J" fixed core
007045	PTFE coated guide wires .035" 120cm straight fixed core
007046	PTFE coated guide wires .035" 145cm straight fixed core
007048	PTFE coating guide wires .038" 145cm straight fixed core
007051	PTFE coated guide wires .035" 145cm straight moveable core
007053	PTFE coated guide wires .038" 145cm straight moveable core
007054	PTFE coated guide wires .038" 145cm 3mm "J" moveable core
007441	PTFE coated guide wires .035" 145cm 6mm "J" fixed core
007443	PTFE coated guide wires .038" 145cm 6mm "J" fixed core
007445	PTFE coated guide wires .035" 145cm 6mm "J" moveable core
007446	PTFE coated guide wires .035" 120cm 3mm "J" moveable core
007447	PTFE coated guide wires .035" 145cm 3mm moveable core
007467	PTFE coated guide wires .035" 145cm straight fixed core
007468	PTFE coated guide wires .035" 145cm straight fixed core
007471	PTFE coated guide wires .035" 145cm 15mm "J" fixed core
007472	PTFE coated guide wires .038" 145cm 15mm "J" fixed core
007641	PTFE coated guide wires .025" 120cm straight fixed core
007642	PTFE coated guide wires .038" 145cm straight fixed core
007643	PTFE coated guide wires .038" 145cm straight fixed core
007644	PTFE coated guide wires .032" 120cm straight fixed core
007645	PTFE coated guide wires .032" 145cm straight fixed core
007647	PTFE coated guide wires .032" 145cm straight moveable core
007648	PTFE coated guide wires .032" 120cm 3mm "J" moveable core
007649	PTFE coated guide wires .032" 145cm 3mm "J" moveable core

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Model Number	Description
007677	Stainless steel guide wires .021" 100cm 3mm "J" fixed core
007873	Guide wires .038" 45cm straight tip stainless steel fixed core
007874	Guide wires .025" 45cm 3mm "J" stainless steel fixed core
007875	Guide wires .035" 45cm 3mm "J" stainless steel fixed core
008418	PTFE coated guide wire .063" 160cm 6mm "J" fixed core
008529	Guide wires .035" 45cm dbl. distal stainless steel movable core
008627	PTFE coated guide wires .035" 175cm 3mm "J" fixed core
008628	PTFE coated guide wires .038" 175cm 3mm "J" fixed core
008629	PTFE coated guide wires .035" 175cm 175cm straight fixed core
008630	PTFE coated guide wires .038" 175cm straight fixed core
008631	PTFE coated guide wires .035" 260cm 3mm "J" fixed core
008632	PTFE coated guide wires .038" 260cm straight fixed core
008633	PTFE coated guide wires .035" 260cm straight fixed core
008634	PTFE coated guide wires .038" 260cm 3mm "J" fixed core
008879	Guide wires .021" 15cm straight tip stainless steel fixed core
008944	PTFE coated guide wire .035" 175cm 1.5mm "J" rosen wire fixed core
008945	PTFE coated guide wire .038" 175cm 1.5mm "J" rosen wire fixed core
008952	PTFE coated guide wires .028" 145cm 3mm "J" fixed core
008953	PTFE coated guide wires .032" 145cm 3mm "J" fixed core
010003	PTFE coated guide wires .035" 145cm 3mm "J" fixed core LT wire
010004	PTFE coated guide wires .038" 145cm 3mm "J" fixed core LT wire
010037	Steerable guide wires w/steering handle PTFE coated .035" 145cm flexible tip fixed core
010038	Steerable guide wires w/steering handle PTFE coated .038" 145cm flexible tip fixed core
010387	PTFE coated guide wires .025" 145cm straight fixed core
010388	PTFE coated guide wires .025" 145cm 3mm "J" fixed core
010439	Guide wires .025" 45cm straight tip stainless steel fixed core
010440	Guide wires .035" 45cm straight tip stainless steel fixed core
007001	Stainless steel guide wires .035" 145cm 3mm "J" fixed core
007003	Stainless steel guide wires .038" 145cm 3mm "J" fixed core
007004	Stainless steel guide wires .025" 70cm straight fixed core
007005	Stainless steel guide wires .025" 100cm straight fixed core
007006	Stainless steel guide wires .025" 120cm straight fixed core
007007	Stainless steel guide wires .025" 145cm straight fixed core
007008	Stainless steel guide wires .035" 70cm straight fixed core
007009	Stainless steel guide wires .035" 100cm straight fixed core
007010	Stainless steel guide wires .035" 120cm straight fixed core
007011	Stainless steel guide wires .035" 145cm straight fixed core
007017	Stainless steel guide wires .035" 145cm straight moveable core
007025	Stainless steel guide wires .035" 145cm 6mm "J" fixed core
007029	Stainless steel guide wires .035" 145cm 3mm moveable core

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Model Number	Description
007040	Stainless steel guide wires .035" 220cm straight fixed core
007615	Stainless steel guide wires .038" 80cm straight fixed core
007627	Stainless steel guide wires .032" 145cm straight fixed core
007632	Stainless steel guide wires .021" 100cm straight fixed core
007676	Stainless steel guide wires .021" 70cm 3mm "J" fixed core
007678	Stainless steel guide wires .021" 70cm straight fixed core
008756	Stainless steel guide wires .018" 80cm straight fixed core
008758	Stainless steel guide wires .018" 145cm straight fixed core

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Revision D

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Revision History

Revision	Date	Description of Change
01	November 11 th , 2010	Updated formatting of Notified Body name and added verbiage that manufacturer is “exclusively responsible for the declaration of conformity”.
02	December 2 nd , 2010	Updated the DoC with the new G1 certificate
03	March 30 th , 2011	Added Rule 6 to classification section
04	May 1 th , 2012	Remove S.A designation from CEA Global Dominicana description in Manufacturing Site section of document
05	August 21 st , 2012	Updated name to Angiographic Guide Wires from Angiography Guidewires
06	December 23, 2014	Remove Persuader Guidewires from the Products list. Add reference to new EC design examination certificate and Full Quality Assurance certificate issued in December 2014. Add information related to compliance to EU harmonized standards.
07	February 10, 2015	Remove legal manufacturing facility information.
08	August 31, 2015	Add “N.E.” to Medtronic, Inc.’s address. Replace “EN ISO 13485: 2012” with “EN ISO 13485: 2012/ AC: 2012”.
09	October 6, 2017	Update the DoC to revise the name and title of the person approving the Declaration of Conformity
10	March 26, 2019	Revised the ISO Standard from ISO 13485: 2012- EN ISO 13485:2016 to reflect compliance to the EN ISO 13485:2016 standard
A	August 14, 2019	Updated EC Quality certificate number to reflect the new certificate number, issuance & expiry date. Updated header & other administrative information to comply with latest FTDOP116978-13 Rev AA.
B	December 19, 2019	Updated EC Certificate number to reflect the new certificate number, issuance and expiry date. And remove LV wires model numbers to align with new EC certificate.
C	June 26 th , 2020	Updated EC Quality Certificate number to reflect the new certificate number, issuance & expiry date
D	May 19, 2021	Corrected the zip code for CEA Global located in the Dominican Republic. Updated Product Families to align with the EC certificate Updated the name of both products to align with what is stated on the EC certificate

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FTDOP116978-13 Rev AC



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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 1357 Rev. 00

Manufacturer:

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis, MN 55432
USA

Product Category(ies): **Temporary Occlusion and Aspiration
System; Angioplasty and Angiography
Products (Angiography Catheters, Guiding
Catheters, Diagnostic Catheters,
Guidewires, Introducers)**

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.:

1466189

Valid from:

2020-06-23

Valid until:

2024-05-26

Date,

2020-06-23

Christoph Dicks
Head of Certification/Notified Body

Zertifizierungsvertrag

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an (www.tuev-sued.de/ps_regulations) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

Certification contract

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations (www.tuv-sud.com/ps_regulations) and thus becomes partner in the TÜV SÜD Product Service Certification System.

Requirements for the validity of the certificate in principle:

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

认证合约

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 www.tuv-sud.com/ps_regulations）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

维持证书有效性的原则要求：

- 认证所依据标准的有效性
- 此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
 - 生产场地通过定期的监督

認証契約

認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約(www.tuv-sud.com/ps_regulations)に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

認証書の有効性に関する原則的な要求事項

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
 - 定期的な工場監査を実施している

Contrato de certificação

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD (www.tuv-sud.com/ps_regulations) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

Requisitos para a validade do certificado (em princípio):

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
 - Auditoria de monitoração realizada regularmente.



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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 039709 0970 Rev. 01

Manufacturer:

Medtronic, Inc.

710 Medtronic Parkway
Minneapolis MN 55432
USA

Product:

Guidewires

**Cardiovascular PTCA and Angiographic
Guidewires**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.:

713155072

Valid from:

2020-01-01

Valid until:

2024-05-26

Date,

2019-12-19

Christoph Dicks

Head of Certification/Notified Body

EC Certificate

EC Design-Examination Certificate

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

(Devices in Class III)

No. G7 039709 0970 Rev. 01

Facility(ies):

Medtronic, Inc.

710 Medtronic Parkway, Minneapolis MN 55432, USA

Model(s):

Cardiovascular Angiography Guide Wires

Cardiocascular PTCA Guide Wires

Parameters:

Cardiovascular Angiography Guide Wires

Model Number	Description
002501	PTFE coated guide wires .035" 145cm 3mm "J" fixed core
002502	PTFE coated guide wires .038" 145cm 3mm "J" fixed core
002503	PTFE coated guide wires .035" 145 cm straight fixed core
006200	SOS open ended GW .038" 145 cm straight standard taper core
006201	SOS open ended GW .038" 145 cm straight long taper core
006203	SOS open ended GW .035" 145 cm straight standart taper core
006204	SOS open ended GW .035" 145 cm straight long taper core
006210	Removable Luer Lock Hub SOS Wires
006305	Soft wire guide wires .035" 145cm straight PTFE coated fixed core
006307	Soft wire guide wires .038" 145cm straight PTFE coated fixed core
007001	Stainless steel guide wires .035" 145cm 3mm "J" fixed core
007003	Stainless steel guide wires .038" 145cm 3mm "J" fixed core
007004	Stainless steel guide wires .025" 70cm straight fixed core
007005	Stainless steel guide wires .025" 100cm straight fixed core
007006	Stainless steel guide wires .025" 120cm straight fixed core
007007	Stainless steel guide wires .025" 145cm straight fixed core
007008	Stainless steel guide wires .035" 70cm straight fixed core
007009	Stainless steel guide wires .035" 100cm straight fixed core
007010	Stainless steel guide wires .035" 120cm straight fixed core
007011	Stainless steel guide wires .035" 145cm straight fixed core
007017	Stainless steel guide wires .035" 145cm straight moveable core
007025	Stainless steel guide wires .035" 145cm 6mm "J" fixed core
007029	Stainless steel guide wires .035" 145cm 3mm moveable core
007040	Stainless steel guide wires .035" 220cm straight fixed core
007041	PTFE coated guide wires .035" 120cm 3mm "J" fixed core
007042	PTFE coated guide wires .035" 145cm 3mm "J" fixed core
007043	PTFE coated guide wires .038" 120cm 3mm "J" fixed core
007044	PTFE coated guide wires .038" 145cm 3mm "J" fixed core
007045	PTFE coated guide wires .035" 120cm straight fixed core
007046	PTFE coated guide wires .035" 145cm straight fixed core
007048	PTFE coating guide wires .038" 145cm straight fixed core



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Product Service

EC Certificate

EC Design-Examination Certificate

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

(Devices in Class III)

No. G7 039709 0970 Rev. 01

007051	PTFE coated guide wires .035" 145cm straight moveable core
007053	PTFE coated guide wires .038" 145cm straight moveable core
007054	PTFE coated guide wires .038" 145cm 3mm "J" moveable core
007441	PTFE coated guide wires .035" 145cm 6mm "J" fixed core
007443	PTFE coated guide wires .038" 145cm 6mm "J" fixed core
007445	PTFE coated guide wires .035" 145cm 6mm "J" moveable core
007446	PTFE coated guide wires .035" 120cm 3mm "J" moveable core
007447	PTFE coated guide wires .035" 145cm 3mm movable core
007467	PTFE coated guide wires .035" 145cm straight fixed core
007468	PTFE coated guide wires .035" 145cm straight fixed core
007471	PTFE coated guide wires .035" 145cm 15mm "J" fixed core
007472	PTFE coated guide wires .038" 145cm 15mm "J" fixed core
007615	Stainless steel guide wires .038" 80cm straight fixed core
007627	Stainless steel guide wires .032" 145cm straight fixed core
007632	Stainless steel guide wires .021" 100cm straight fixed core
007641	PTFE coated guide wires .025" 120cm straight fixed core
007642	PTFE coated guide wires .038" 145cm straight fixed core
007643	PTFE coated guide wires .038" 145cm straight fixed core
007644	PTFE coated guide wires .032" 120cm straight fixed core
007645	PTFE coated guide wires .032" 145cm straight fixed core
007647	PTFE coated guide wires .032" 145cm straight moveable core
007648	PTFE coated guide wires .032" 120cm 3mm "J" moveable core
007649	PTFE coated guide wires .032" 145cm 3mm "J" moveable core
007676	Stainless steel guide wires .021" 70cm 3mm "J" fixed core
007677	Stainless steel guide wires .021" 100cm 3mm "J" fixed core
007678	Stainless steel guide wires .021" 70cm straight fixed core
007873	Guide wires .038" 45cm straight tip stainless steel fixed core
007874	Guide wires .025" 45cm 3mm "J" stainless steel fixed core
007875	Guide wires .035" 45cm 3mm "J" stainless steel fixed core



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Product Service

EC Certificate

EC Design-Examination Certificate

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

(Devices in Class III)

No. G7 039709 0970 Rev. 01

008418	PTFE coated guide wire .063" 160cm 6mm "J" fixed core
008529	Guide wires .035" 45cm dbl. distal stainless steel movable core
008627	PTFE coated guide wires .035" 175cm 3mm "J" fixed core
008628	PTFE coated guide wires .038" 175cm 3mm "J" fixed core
008629	PTFE coated guide wires .035" 175cm 175cm straight fixed core
008630	PTFE coated guide wires .038" 175cm straight fixed core
008631	PTFE coated guide wires .035" 260cm 3mm "J" fixed core
008632	PTFE coated guide wires .038" 260cm straight fixed core
008633	PTFE coated guide wires .035" 260cm straight fixed core
008634	PTFE coated guide wires .038" 260cm 3mm "J" fixed core
008756	Stainless steel guide wires .018" 80cm straight fixed core
008758	Stainless steel guide wires .018" 145cm straight fixed core
008879	Guide wires .021" 15cm straight tip stainless steel fixed core
008944	PTFE coated guide wire .035" 175cm 1.5mm "J" rosen wire fixed core
008945	PTFE coated guide wire .038" 175cm 1.5mm "J" rosen wire fixed core
008952	PTFE coated guide wires .028" 145cm 3mm "J" fixed core
008953	PTFE coated guide wires .032" 145cm 3mm "J" fixed core
010003	PTFE coated guide wires .035" 145cm 3mm "J" fixed core LT wire
010004	PTFE coated guide wires .038" 145cm 3mm "J" fixed core LT wire
010037	Steerable guide wires w/steering handle PTFE coated .035" 145cm flexible tip fixed core
010038	Steerable guide wires w/steering handle PTFE coated .038" 145cm flexible tip fixed core
010387	PTFE coated guide wires .025" 145cm straight fixed core
010388	PTFE coated guide wires .025" 145cm 3mm "J" fixed core
010439	Guide wires .025" 45cm straight tip stainless steel fixed core
010440	Guide wires .035" 45cm straight tip stainless steel fixed core

EC Certificate

EC Design-Examination Certificate

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

(Devices in Class III)

No. G7 039709 0970 Rev. 01

Cardiovascular PTCA Guide Wires:

Product	Product Code Or Model Numbers	Length (cm)	Coating (Proximal Corewire)	Coating (Distal section)	Tip shape
Cougar Light Support					
Cougar LS	CGRLS190HJ	190 cm	PTFE coating	Hydro-Track	J-Tip
Cougar LS	CGRLS190HS	190 cm	PTFE coating	Hydro-Track	Straight Tip
Cougar LS	CGRLS190J	190 cm	PTFE coating	Pro/Pel	J-Tip
Cougar LS	CGRLS190S	190 cm	PTFE coating	Pro/Pel	Straight Tip
Cougar LS	CGRLS300HJ	300 cm	PTFE coating	Hydro-Track	J-Tip
Cougar LS	CGRLS300HS	300 cm	PTFE coating	Hydro-Track	Straight Tip
Cougar LS	CGRLS300J	300 cm	PTFE coating	Pro/Pel	J-Tip
Cougar LS	CGRLS300S	300cm	PTFE coating	Pro/Pel	Straight Tip
Cougar Medium					
Cougar XT	CGRXT190HJ	190 cm	PTFE coating	Hydro-Track	J-Tip
Cougar XT	CGRXT190HS	190 cm	PTFE coating	Hydro-Track	Straight Tip
Cougar XT	CGRXT190J	190 cm	PTFE coating	Pro/Pel	J-Tip
Cougar XT	CGRXT190S	190 cm	PTFE coating	Pro/Pel	Straight Tip
Cougar XT	CGRXT300HJ	300 cm	PTFE coating	Hydro-Track	J-Tip
Cougar XT	CGRXT300HS	300 cm	PTFE coating	Hydro-Track	Straight Tip
Cougar XT	CGRXT300J	300 cm	PTFE coating	Pro/Pel	J-Tip
Cougar XT	CGRXT300S	300 cm	PTFE coating	Pro/Pel	Straight Tip
Thunder					
Thunder	THNDR190J	190 cm	PTFE coating	Pro/Pel	J-Tip
Thunder	THNDR190S	190 cm	PTFE coating	Pro/Pel	Straight Tip
Thunder	THNDR300J	300 cm	PTFE coating	Pro/Pel	J-Tip
Thunder	THNDR300S	300 cm	PTFE coating	Pro/Pel	Straight Tip
Zinger Light Support					
Zinger LS	ZNGRLS180HJ	180 cm	PTFE coating	Hydro-Track	J-Tip
Zinger LS	ZNGRLS180HS	180 cm	PTFE coating	Hydro-Track	Straight Tip
Zinger LS	ZNGRLS180J	180 cm	PTFE coating	Pro/Pel	J-Tip
Zinger LS	ZNGRLS180S	180 cm	PTFE coating	Pro/Pel	Straight Tip
Zinger LS	ZNGRLS300HJ	300 cm	PTFE coating	Hydro-Track	J-Tip
Zinger LS	ZNGRLS300HS	300 cm	PTFE coating	Hydro-Track	Straight Tip
Zinger LS	ZNGRLS300J	300 cm	PTFE coating	Pro/Pel	J-Tip
Zinger LS	ZNGRLS300S	300 cm	PTFE coating	Pro/Pel	Straight Tip



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Product Service

EC Certificate

EC Design-Examination Certificate

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

(Devices in Class III)

No. G7 039709 0970 Rev. 01

Product	Product Code Or Model Numbers	Length (cm)	Coating (Proximal Corewire)	Coating (Distal section)	Tip shape
ProVia 3					
ProVia 3	3PROV180HS	180 cm	PTFE coating	Hydro-Track	Straight Tip
ProVia 3	3PROV180SS	180 cm	PTFE coating	Pro/Pel	Straight Tip
ProVia 3	3PROV300HS	300 cm	PTFE coating	Hydro-Track	Straight Tip
ProVia 3	3PROV300SS	300 cm	PTFE coating	Pro/Pel	Straight Tip
ProVia 6					
ProVia 6	6PROV180HS	180 cm	PTFE coating	Hydro-Track	Straight Tip
ProVia 6	6PROV180SS	180 cm	PTFE coating	Pro/Pel	Straight Tip
ProVia 6	6PROV300HS	300 cm	PTFE coating	Hydro-Track	Straight Tip
ProVia 6	6PROV300SS	300 cm	PTFE coating	Pro/Pel	Straight Tip
ProVia 9					
ProVia 9	9PROV180HS	180 cm	PTFE coating	Hydro-Track	Tapered Tip
ProVia 9	9PROV180SS	180 cm	PTFE coating	Pro/Pel	Tapered Tip
ProVia 9	9PROV300HS	300 cm	PTFE coating	Hydro-Track	Tapered Tip
ProVia 9	9PROV300SS	300 cm	PTFE coating	Pro/Pel	Tapered Tip
ProVia 12					
ProVia 12	12PROV180HS	180 cm	PTFE coating	Hydro-Track	Tapered Tip
ProVia 12	12PROV180SS	180 cm	PTFE coating	Pro/Pel	Tapered Tip
ProVia 12	12PROV300HS	300 cm	PTFE coating	Hydro-Track	Tapered Tip
ProVia 12	12PROV300SS	300 cm	PTFE coating	Pro/Pel	Tapered Tip
ProVia 15					
ProVia 15	15PROV180HS	180 cm	PTFE coating	Hydro-Track	Tapered Tip
ProVia 15	15PROV180SS	180 cm	PTFE coating	Pro/Pel	Tapered Tip
ProVia 15	15PROV300HS	300 cm	PTFE coating	Hydro-Track	Tapered Tip
ProVia 15	15PROV300SS	300 cm	PTFE coating	Pro/Pel	Tapered Tip