

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr.1 din 06.10.2023

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:

- Absorbable Sutures and Non Absorbable Sutures

Se anexează următoarele acte:

Declarație pe proprie răspundere

CE certificate

Declarație de conformitate

Scrisoare de imputernicire

Data 06/10/2023

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:

- Absorbable Sutures and Non Absorbable Sutures
Sunt autentice și corespund realității.

Numele, prenumele și funcția

Kojevnikov Dmitrii, director

Semnătura _____

Data 06/10/2023

Medtronic

Medtronic META FZ-LLC

Injaz Building, 3rd floor

Dubai Knowledge Park, P.O. Box
500638

Dubai, United Arab Emirates

www.medtronic.com

Tel : +971 4 818 2666

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 See 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 Deggendorf, 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-Bót 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, Libriamiento a la P, La Mesa Tijuana, B.C., Mexico
- Calle 9 Sur No. 125 Ciudad 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 Opglabbeek, 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 Chenhang 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 Morais 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 Sebastião. Paraíso, Minas Gerais, Cep: 37950-000 Brasil

March 4, 2022

To Whom It May Concern,

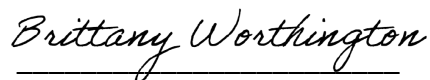
We Covidien llc, a legal entity located at 15 Hampshire Street, Mansfield, MA 02048, have a fast absorbing braided suture to our Wound Closure portfolio.

The product is purchased from OEM (Original Equipment Manufacturer) Riverpoint Medical llc, 825 NE 25th Avenue Portland, OR 97232, USA.

Riverpoint Medical llc provides the final product private labeled as Velosorb™ Fast Suture.

Covidien llc has a distribution contract with Riverpoint Medical llc and the final product label reflects the relationship of Riverpoint Medical llc as the manufacturer and the product being manufactured for Covidien llc.

Signed on behalf of Covidien,



Brittany Worthington
Regulatory Affairs Specialist



Declaration of Conformity

Swaged Surgical Sutures

Applications of Council Directive: 93/42/EEC Medical Devices Directive	CE
Certificate number:	24789 (Annex II.3) 24790 (Annex II.4)
Notified Body:	GMED SAS, 0459 1, rue Gaston Boissier 75015 PARIS France
Standards to which conformity is declared:	See Essential Requirements Checklist DSA0102
Manufacturer's name and address:	Riverpoint Medical LLC 825 NE 25th Ave. Portland, OR 97232 USA
Authorized Representative:	Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands
Type of Equipment:	See attached list (pages 2 and 3)
Model Number(s):	See attached list (pages 2 and 3).
Technical Documentation File Location:	Riverpoint Medical LLC 825 NE 25th Ave. Portland, OR 97232 USA

I, the undersigned, hereby declare that the device specified above conforms to the above Directive(s) and Standard(s).

Name: Edwin Anderson
Position: VP of Regulatory Affairs and Quality Assurance
Company: Riverpoint Medical
Date: March 19, 2021
Expiration: March 22, 2024

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits

3/24/2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed



Product Code Listings – Absorbable Sutures

The Riverpoint sterile surgical sutures product line includes various product codes based on suture type, size, needle combination and configuration. Rule 8, implantable, Long-Term use in contact with the heart, central circulatory system or the central nervous system (worst case classification). Class III, Directive 93/42/EEC Annex II.3/II.4 Conformity Assessment

- Vilet (PGLA) - Vxxx (xxx = sizes 8/0 – 3 USP (0.4 – 6.0 metric), dyed with FD&C No. 2 (violet) or undyed; various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).
- Velosorb™ Fast - CVxxxx (G) CV= closure Velosorb; xxxx = sequentially assigned numbers, 0000-9999
(PGLA Quick) SV(P)xxxx(G) SV= subcuticular Velosorb; xxxx = sequentially assigned numbers, 0000-9999
UVxxxx(G) UV= urology Velosorb; xxxx = sequentially assigned numbers, 0000-9999
- Mono Q (PGCL) - Qxxx (xxx = sizes 7/0 – 2 USP (0.5 – 5.0 metric), dyed with FD&C No. 2 (violet) or undyed; various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).
- PDM (PDO) - Dxxx (xxx = sizes 7/0 – 2 USP (0.5 – 5.0 metric), dyed with FD&C No. 2 (violet) or undyed; various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).
- Vilet II (PGA) - VGxxx (xxx = sizes 8/0 – 6 USP (0.4 – 8.0 metric), dyed with FD&C No. 2 (violet) or undyed; various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits
Abdelhak 3/24/2021
 GMED (0459) recognizes that its EC certificate is valid for the medical devices listed



Product Code Listings – Non Absorbable Sutures

Product code ranges are listed below. All number combinations which fall between the numbers listed are applicable product codes for each product type when used in combination with the letters shown. Rule 8, implantable, Long-Term use in contact with the heart, central circulatory system or the central nervous system (worst case classification). Class III, Directive 93/42/EEC Annex II.3/II.4 Conformity Assessment

RiverPro (polypropylene) –	Pxxxx	(xxx = sizes 10/0 - 2 USP (0.2 – 5.0 metric), dyed with [Phthalocyaninato (2-)] copper (blue) or undyed; various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).
RiverBond (polyester) –	PBxxxx	(xxx = sizes 6/0 - 5 USP (0.7 – 7.0 metric), dyed with D&C Green No. 6 (Green) or undyed; various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).
RiverLon (nylon) –	xxxxBL or xxxBK	(xxx = sizes 11/0 - 2 USP (0.1 – 5.0 metric), dyed with Logwood (black) of FD&C Blue No. 2 (blue) or undyed; various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).
MonoTex (PTFE) –	Txxxx	(xxx = sizes 6/0 - 5 USP (0.7 – 7.0 metric), undyed various medical grade suture needles composed of type 300 or type 400 stainless steel attached per customer).

GMED (0459) reconnait que son certificat CE est valide pour les dispositifs médicaux décrits

 3/24/2021

GMED (0459) recognizes that its EC certificate is valid for the medical devices listed



ATTESTATION / CERTIFICATE N° 24789 rev. 7

Délivrée à Paris le 14 mai 2020

Issued in Paris on May 14th, 2020

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

RIVERPOINT MEDICAL LLC

825 NE 25th Avenue

PORTLAND, OR 97232 UNITED STATES

Catégorie du(des) dispositif(s) / Device(s) category

Sutures résorbables et non résorbables

Absorbable and non-Absorbable sutures

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé T000384ER, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

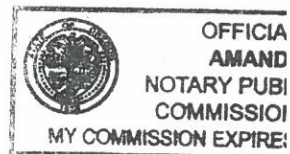
GMED certifies that, on the basis of the results contained in the file referenced T000384ER, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue

The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : **May 14th, 2020 (included)**

Valable jusqu'au / Expiry date : **May 26th, 2024 (included)**



On behalf of the President

Béatrice LYS

Technical Director



Addendum au certificat n° 24789 rev. 7 page 1/1
 Addendum of the certificate n° 24789 rev. 7
 Dossier / File N° T000384ER

Identification des dispositifs / Identification of devices

Catégorie du dispositif médical Medical Device Category	Dénomination Commerciale Commercial Reference	Class to DM Md Class
Sutures résorbables Absorbable sutures	Vilet (PGLA) Vilet Quick (PGLA) Velosorb™ (Fast)(PGLA Quick) Mono Q (PGCL) PDM (PDO) Vilet II (PGA) Vilet II Quick (PGA)	III
Sutures non résorbables Non-Absorbable sutures	RiverPro (polypropylene) RiverBond (polyester) RiverLon (nylon) RiverSilk (silk) PTFE Swaged Sutures (Mono Tex) (Polytetrafluoroethylene)	
	HS Fiber (polyblend)	IIb

Les produits couverts par ce certificat sont référencés
 sur la liste de produits authentifiée par le G-MED le 28 Octobre 2019

The products covered by this certificate are listed
 on the list of products authenticated by G-MED on October 28th, 2019

Ce certificat couvre le site suivant et activités:

This certificate covers the following sites and activities:

Riverpoint Medical LLC
 825 NE 25th Avenue
 Portland, OR 97232 - USA

Conception, fabrication et contrôle final / Design, manufacturing and final control

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 OREGON
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 GUST 23, 2022

GMED 0459



On behalf of the President
Béatrice LYS
 Technical Director

State of **OREGON**

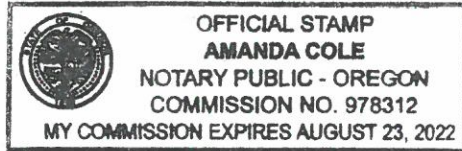
County of **MULTNOMAH**

This record was acknowledged before me on 01 September, 20 20

by Eileen McCafferty.



Notary Public – State of Oregon



ATTESTATION CE / EC CERTIFICATE

Examen CE de la Conception (du produit) / EC Design Examination (of the product)

ANNEXE II point 4 de la directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II section 4 DIRECTIVE 93/42/EEC concerning medical devices

Fabricant / Manufacturer

RIVERPOINT MEDICAL LLC
825 NE 25th Avenue
PORTLAND, OR 97232 UNITED STATES

Catégorie du(des) dispositif(s) / Device(s) category

Sutures résorbables et non résorbables

Absorbable and non-Absorbable sutures

Identification du(des) dispositif(s) / Identification of device(s)

Voir Addendum

See Addendum

Voir document complémentaire GMED / See GMED additional document

n° 38235

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) T001247, le(s) produit(s) énuméré(s) ci-dessus est (sont) conforme(s) aux exigences de l'annexe I de la directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file(s) referenced T001247, the product(s) complie(s) with the requirements of the directive 93/42/EEC, annex 1

Début de validité / Effective date : March 24th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)



DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

GMED - 24790 rev. 11
Renouvelle le certificat 24790-10

Ce document complémentaire GMED n° 38235 rev. 0 atteste de la validité du certificat CE n° 24790 rev. 11 au regard des informations listées ci-dessous.

This GMED additional document N° 38235 rev. 0 attests to the validity of CE certificate n° 24790 rev. 11 with regard to the information listed below.

Fabricant / Manufacturer: RIVERPOINT MEDICAL LLC
825 NE 25th Avenue
PORTLAND, OR 97232 UNITED STATES

Identification des dispositifs / Identification of devices

Catégorie du dispositif médical <i>Medical Device Category</i>	Dénomination Commerciale <i>Commercial Reference</i>	GMDN Code	Class to DM <i>Md Class</i>
Sutures résorbables <i>Absorbable sutures</i>	Vilet (PGLA)	17471	III
	Velosorb™ (Fast)(PGLA Quick)	17471	
	Mono Q (PGCL)	45814	
	PDM (PDO)	16584	
	Vilet II (PGA)	13908	
Sutures non résorbables <i>Non-Absorbable sutures</i>	RiverPro (polypropylene)	13909	
	RiverBond (polyester)	13906	
	RiverLon (nylon)	37997, 38000	
	PTFE Swaged Sutures (Mono Tex) (Polytetrafluoroethylene)	17467	

Les produits couverts par ce certificat sont de classe III et sont référencés sur la liste de produits authentifiée par le G-MED le 24 mars 2021

The products covered by this certificate are class III and are listed on the list of products authenticated by G-MED on March 24th, 2021



GMED – 38235 rev. 0



DocuSigned by:
Beatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director