

Către
Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 3 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:

- CORNERSTONE-SR™ Cage System (Implants)

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:

- CORNERSTONE-SR™ Cage System (Implants)
Sunt autentice și corespund realității.

Numele, prenumele și funcția

Kojevnikov Dmitrii, director

Semnătura _____

Data 01/10/2023

TO WHOM IT MAY CONCERN

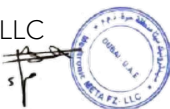
Date: 29.05.2023

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 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

TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
USA

MEDICAL DEVICE:

Cervical Fusion bundle
Technical File TF008
Reference Product List including GMDN and UMDNS codes

CLASSIFICATION IN ACCORDANCE WITH ANNEX IX:

Class IIa, Rule 6; Class IIb, Rule 8
Reference Product List for specific device classifications

CONFORMITY ASSESSMENT ROUTE:

Annex II (excluding Section 4)
Reference Product List for specific device routes

WE, THE MANUFACTURER, UNDER OUR SOLE RESPONSIBILITY, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, OF THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC AND IF APPLICABLE, COMMISSION REGULATION NO. 722/2012.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: REFER TO LIST OF HARMONISED – EN STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. THIS LIST IS LOCATED WITH THE TECHNICAL FILE.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MUNICH, GERMANY

IDENTIFICATION NUMBER:

0123 for Class IIa and IIb

(EC) CERTIFICATE(S):

G1 039040 0078

Exp Date: 26-May-2024



EUROPEAN REPRESENTATIVE:

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

START OF CE-MARKING:

DATE OF FIRST CE MARKING (Reference attached list)

SIGNATURE:

Claire Evans

DATE

PLACE:

Sr Regulatory Affairs Manager
Memphis, TN USA

Product List

Last updated by: Lila Joe

Date: 2/22/2021

Tech File Bundle: Cervical Fusion, TF008

Product: Instruments, Non-Sterile and Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
875-087	12mm DISTRATOR PIN	Mar-00	Rule 6	Annex II (excluding section 4)	56637	11291
875-088	14mm DISTRATOR PIN	Mar-00	Rule 6	Annex II (excluding section 4)	56637	11290
875-089	16mm DISTRATOR PIN	Mar-00	Rule 6	Annex II (excluding section 4)	56637	11291
3034001	Adjustable Drill Bit, Sterile	Jun-15	Rule 6	Annex II (excluding section 4)	43390	11331
7080510	11 MM DRILL BIT STERILE	Sep-06	Rule 6	Annex II (excluding section 4)	43390	11331
7080513	DRILL BIT STERILE 13MM	Sep-10	Rule 6	Annex II (excluding section 4)	43390	11331
876-443	13MM DRILL BIT, STERILE	Sep-02	Rule 6	Annex II (excluding section 4)	43390	11331
876-455	ADJUSTABLE DRILL BIT STERILE	Sep-02	Rule 6	Annex II (excluding section 4)	43390	11331
9790915	DRILL BIT 11MM STERILE	Aug-04	Rule 6	Annex II (excluding section 4)	43390	11331
6212445	DUAL END TRIAL 14X11X4/5	Oct-11	Rule 6	Annex II (excluding section 4)	44788	13180
6212467	DUAL END TRIAL 14X11X6/7	Oct-11	Rule 6	Annex II (excluding section 4)	44788	13180
6212489	DUAL END TRIAL 14X11X8/9	Oct-11	Rule 6	Annex II (excluding section 4)	44788	13180
6212645	DUAL END TRIAL 16X14X4/5	Oct-11	Rule 6	Annex II (excluding section 4)	44788	13180
6212667	DUAL END TRIAL 16X14X6/7	Oct-11	Rule 6	Annex II (excluding section 4)	44788	13180
6212845	DUAL END TRIAL 18X16X4/5	Oct-11	Rule 6	Annex II (excluding section 4)	44788	13180
6212867	DUAL END TRIAL 18X16X6/7	Oct-11	Rule 6	Annex II (excluding section 4)	44788	13180
6274041	TRASP 10X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274141	TRASP 11X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274241	TRASP 12X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274341	TRASP 13X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274411	TRASP 4X11X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274441	TRASP 4X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274444	TRASP 4X14X14, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274511	TRASP 5X11X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274541	TRASP 5X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274544	TRASP 5X14X14, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274611	TRASP 6X11X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274641	TRASP 6X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274644	TRASP 6X14X14, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274711	TRASP 7X11X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274741	TRASP 7X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274744	TRASP 7X14X14, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274811	TRASP 8X11X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274841	TRASP 8X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274844	TRASP 8X14X14, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274911	TRASP 9X11X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274941	TRASP 9X14X11, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6274944	TRASP 9X14X14, 4 DEGREE	Jan-06	Rule 6	Annex II (excluding section 4)	44788	13180
6276414	4MM X 14MM X 11MM TRIAL	Sep-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276415	5MM X 14MM X 11MM TRIAL	Apr-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276416	6MM X 14MM X 11MM TRIAL	Apr-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276417	7MM X 14MM X 11MM TRIAL	Apr-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276418	8MM X 14MM X 11MM TRIAL	Apr-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276419	9MM X 14MM X 11MM TRIAL	Sep-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276514	4X14X11 ANATOMICAL TRIAL	Jul-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276515	5X14X11 ANATOMICAL TRIAL	Jul-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276516	6X14X11 ANATOMICAL TRIAL	Jul-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276517	7X14X11 ANATOMICAL TRIAL	Jul-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276518	8X14X11 ANATOMICAL TRIAL	Jul-03	Rule 6	Annex II (excluding section 4)	44788	13180

Product: Instruments, Non-Sterile and Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6276519	9X14X11 ANATOMICAL TRIAL	Sep-03	Rule 6	Annex II (excluding section 4)	44788	13180
6276744	17X14X4 ANATOMICAL TRIAL	Nov-04	Rule 6	Annex II (excluding section 4)	44788	13180
6276745	17X14X5 ANATOMICAL TRIAL	Nov-04	Rule 6	Annex II (excluding section 4)	44788	13180
6276746	17X14X6 ANATOMICAL TRIAL	Nov-04	Rule 6	Annex II (excluding section 4)	44788	13180
6276747	17X14X7 ANATOMICAL TRIAL	Nov-04	Rule 6	Annex II (excluding section 4)	44788	13180
6276748	17X14X8 ANATOMICAL TRIAL	Nov-04	Rule 6	Annex II (excluding section 4)	44788	13180
6276749	17X14X9 ANATOMICAL TRIAL	Nov-04	Rule 6	Annex II (excluding section 4)	44788	13180
8740041	10X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740044	10X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740141	11X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740144	11X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740241	12X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740244	12X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740344	13X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740541	5X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740544	5X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740641	6X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740644	6X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740741	7X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740744	7X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740841	8X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740844	8X14X14 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
8740941	9X14X11 CORNERSTONE SR TRIAL	Jun-05	Rule 6	Annex II (excluding section 4)	44788	13180
974-141	C'STONE TRIAL, LORD, 11X14X11	Jan-04	Rule 6	Annex II (excluding section 4)	44788	13180
974-241	C'STONE TRIAL, LORD, 12X14X11	Jan-04	Rule 6	Annex II (excluding section 4)	44788	13180
974-341	C'STONE TRIAL, LORD, 13X14X11	Jan-04	Rule 6	Annex II (excluding section 4)	44788	13180
974-544	C-STONE TRIAL, LORD, 5X14X14	Jan-04	Rule 6	Annex II (excluding section 4)	44788	13180
DIVERGENCE						
77305256	DIVERGENCE Parallel IB Trial, 5mm-6mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77305456	DIVERGENCE Parallel IB Trial, 5mm-6mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307456	DIVERGENCE Parallel IB Trial, 5mm-6mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307656	DIVERGENCE Parallel IB Trial, 5mm-6mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302456	DIVERGENCE Parallel IB Trial, 5mm-6mm x 20mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302656	DIVERGENCE Parallel IB Trial, 5mm-6mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77305278	DIVERGENCE Parallel IB Trial, 7mm-8mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77305478	DIVERGENCE Parallel IB Trial, 7mm-8mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307478	DIVERGENCE Parallel IB Trial, 7mm-8mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307678	DIVERGENCE Parallel IB Trial, 7mm-8mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302478	DIVERGENCE Parallel IB Trial, 7mm-8mm x 20mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302678	DIVERGENCE Parallel IB Trial, 7mm-8mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180

Product: Instruments, Non-Sterile and Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
77305290	DIVERGENCE Parallel IB Trial, 9mm-10mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77305490	DIVERGENCE Parallel IB Trial, 9mm-10mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307490	DIVERGENCE Parallel IB Trial, 9mm-10mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307690	DIVERGENCE Parallel IB Trial, 9mm-10mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302490	DIVERGENCE Parallel IB Trial, 9mm-10mm x 20mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302690	DIVERGENCE Parallel IB Trial, 9mm-10mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77305212	DIVERGENCE Parallel IB Trial, 11mm-12mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77305412	DIVERGENCE Parallel IB Trial, 11mm-12mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307412	DIVERGENCE Parallel IB Trial, 11mm-12mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77307612	DIVERGENCE Parallel IB Trial, 11mm-12mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302412	DIVERGENCE Parallel IB Trial, 11mm-12mm x 20mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77302612	DIVERGENCE Parallel IB Trial, 11mm-12mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365256	DIVERGENCE Lordotic IB Trial, 5mm-6mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365456	DIVERGENCE Lordotic IB Trial, 5mm-6mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367456	DIVERGENCE Lordotic IB Trial, 5mm-6mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367656	DIVERGENCE Lordotic IB Trial, 5mm-6mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77362656	DIVERGENCE Lordotic IB Trial, 5mm-6mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365278	DIVERGENCE Lordotic IB Trial, 7mm-8mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365478	DIVERGENCE Lordotic IB Trial, 7mm-8mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367478	DIVERGENCE Lordotic IB Trial, 7mm-8mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367678	DIVERGENCE Lordotic IB Trial, 7mm-8mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77362678	DIVERGENCE Lordotic IB Trial, 7mm-8mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365290	DIVERGENCE Lordotic IB Trial, 9mm-10mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365490	DIVERGENCE Lordotic IB Trial, 9mm-10mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367490	DIVERGENCE Lordotic IB Trial, 9mm-10mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367690	DIVERGENCE Lordotic IB Trial, 9mm-10mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180

Product: Instruments, Non-Sterile and Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
77362690	DIVERGENCE Lordotic IB Trial, 9mm-10mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365212	DIVERGENCE Lordotic IB Trial, 11mm-12mm x 15mm x 12mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77365412	DIVERGENCE Lordotic IB Trial, 11mm-12mm x 15mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367412	DIVERGENCE Lordotic IB Trial, 11mm-12mm x 17mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77367612	DIVERGENCE Lordotic IB Trial, 11mm-12mm x 17mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77362412	DIVERGENCE Lordotic IB Trial, 11mm-12mm x 20mm x 14mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
77362612	DIVERGENCE Lordotic IB Trial, 11mm-12mm x 20mm x 16mm	Jan-15	Rule 6	Annex II (excluding section 4)	44788	13180
6630910	9mm Drill Sterile	Jan-15	Rule 6	Annex II (excluding section 4)	43390	11331
6630911	11mm Drill Sterile	Jan-15	Rule 6	Annex II (excluding section 4)	43390	11331
6630912	13mm Drill Sterile	Jan-15	Rule 6	Annex II (excluding section 4)	43390	11331
66205256	SA Parallel Interbody Trial, 5mm-6mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66205456	SA Parallel Interbody Trial, 5mm-6mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207456	SA Parallel Interbody Trial, 5mm-6mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207656	SA Parallel Interbody Trial, 5mm-6mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66202456	SA Parallel Interbody Trial, 5mm-6mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66202656	SA Parallel Interbody Trial, 5mm-6mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66205278	SA Parallel Interbody Trial, 7mm-8mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66205478	SA Parallel Interbody Trial, 7mm-8mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207478	SA Parallel Interbody Trial, 7mm-8mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207678	SA Parallel Interbody Trial, 7mm-8mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66202478	SA Parallel Interbody Trial, 7mm-8mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66202678	SA Parallel Interbody Trial, 7mm-8mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66205290	SA Parallel Interbody Trial, 9mm-10mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66205490	SA Parallel Interbody Trial, 9mm-10mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207490	SA Parallel Interbody Trial, 9mm-10mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207690	SA Parallel Interbody Trial, 9mm-10mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66202490	SA Parallel Interbody Trial, 9mm-10mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180

Product: Instruments, Non-Sterile and Sterile

Class: IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
66202690	SA Parallel Interbody Trial, 9mm-10mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66205212	SA Parallel Interbody Trial, 11mm-12mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66205412	SA Parallel Interbody Trial, 11mm-12mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207412	SA Parallel Interbody Trial, 11mm-12mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66207612	SA Parallel Interbody Trial, 11mm-12mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66202412	SA Parallel Interbody Trial, 11mm-12mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66202612	SA Parallel Interbody Trial, 11mm-12mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66265256	SA Parallel Interbody Trial, 5mm-6mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66265456	SA Parallel Interbody Trial, 5mm-6mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267456	SA Parallel Interbody Trial, 5mm-6mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267656	SA Parallel Interbody Trial, 5mm-6mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262456	SA Parallel Interbody Trial, 5mm-6mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262656	SA Parallel Interbody Trial, 5mm-6mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66265278	SA Parallel Interbody Trial, 7mm-8mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66265478	SA Parallel Interbody Trial, 7mm-8mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267478	SA Parallel Interbody Trial, 7mm-8mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267678	SA Parallel Interbody Trial, 7mm-8mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262478	SA Parallel Interbody Trial, 7mm-8mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262678	SA Parallel Interbody Trial, 7mm-8mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66265290	SA Parallel Interbody Trial, 9mm-10mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66265490	SA Parallel Interbody Trial, 9mm-10mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267490	SA Parallel Interbody Trial, 9mm-10mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267690	SA Parallel Interbody Trial, 9mm-10mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262490	SA Parallel Interbody Trial, 9mm-10mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262690	SA Parallel Interbody Trial, 9mm-10mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66265212	SA Parallel Interbody Trial, 11mm-12mm x 15mm x 12mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180

Product: Instruments, Non-Sterile and Sterile**Class:** IIa

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
66265412	SA Parallel Interbody Trial, 11mm-12mm x 15mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267412	SA Parallel Interbody Trial, 11mm-12mm x 17mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66267612	SA Parallel Interbody Trial, 11mm-12mm x 17mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262412	SA Parallel Interbody Trial, 11mm-12mm x 20mm x 14mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180
66262612	SA Parallel Interbody Trial, 11mm-12mm x 20mm x 16mm	Jun-15	Rule 6	Annex II (excluding section 4)	44788	13180

Product List

Last updated by: Lila Joe

Date: 5/22/2020

Tech File Bundle: Cervical Fusion, TF008

Product: ATLANTIS™ Anterior Cervical Plate System (Implants)

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3120211	4.0 X 11 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120212	4.0 X 12 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120213	4.0 X 13 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120214	4.0 X 14 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120215	4.0 X 15 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120216	4.0 X 16 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120217	4.0 X 17 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120218	4.0 X 18 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120219	4.0 X 19 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120220	4.0 X 20 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120311	4.0 X 11 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120312	4.0 X 12 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120313	4.0 X 13 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120314	4.0 X 14 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120315	4.0 X 15 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120316	4.0 X 16 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120317	4.0 X 17 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120318	4.0 X 18 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120319	4.0 X 19 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120320	4.0 X 20 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120411	4.0 X 11 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120412	4.0 X 12 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120413	4.0 X 13 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120414	4.0 X 14 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120415	4.0 X 15 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120416	4.0 X 16 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120417	4.0 X 17 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120511	4.0 X 11 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120512	4.0 X 12 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120513	4.0 X 13 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120514	4.0 X 14 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120515	4.0 X 15 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120516	4.0 X 16 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3120517	4.0 X 17 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3125211	4.5 X 11 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125213	4.5 X 13 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125215	4.5 X 15 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125217	4.5 X 17 SELF-TAP FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3125311	4.5 X 11 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3125313	4.5 X 13 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125315	4.5 X 15 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3125317	4.5 X 17 SELF-TAP VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125411	4.5 X 11 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125413	4.5 X 13 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3125415	4.5 X 15 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125417	4.5 X 17 SELF-DRILL FIX SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
3125511	4.5 X 11 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125513	4.5 X 13 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125515	4.5 X 15 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	46651	15766
3125517	4.5 X 17 SELF-DRILL VAR SCREW	Sep-08	Rule 8	Annex II (excluding section 4)	61325	15766
6190019	ANTERIOR CERVICAL PLATE 19MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190021	ANTERIOR CERVICAL PLATE 21MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190025	ANTERIOR CERVICAL PLATE 25MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190027	ANTERIOR CERVICAL PLATE 27.5MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190030	ANTERIOR CERVICAL PLATE 30MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190032	ANTERIOR CERVICAL PLATE 32.5MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190035	ANTERIOR CERVICAL PLATE 35MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190037	ANTERIOR CERVICAL PLATE 37.5MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190040	ANTERIOR CERVICAL PLATE 40MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190042	ANTERIOR CERVICAL PLATE 42.5MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190045	ANTERIOR CERVICAL PLATE 45MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190047	ANTERIOR CERVICAL PLATE 47.5MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190050	ANTERIOR CERVICAL PLATE 50MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190052	ANTERIOR CERVICAL PLATE 52.5MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766
6190055	ANTERIOR CERVICAL PLATE 55MM	Sep-08	Rule 8	Annex II (excluding section 4)	46653	15766

Product List

Last updated by: Lila Joe
Tech File Bundle: Cervical Fusion, TF008

Date: 2/22/2021

Product: CORNERSTONE™ PSR Cervical Fusion System (Implants)

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6284541	LATERAL PORTS 5X14X11 SPACER	Apr-12	Rule 8	Annex II (excluding section 4)	61230	15766
6284544	LATERAL PORTS 5X14X14 SPACER	Apr-12	Rule 8	Annex II (excluding section 4)	61230	15766
6284611	LATERAL PORTS 6X11X11 SPACER	Apr-12	Rule 8	Annex II (excluding section 4)	61230	15766
6284641	LATERAL PORTS 6X14X11 SPACER	Apr-12	Rule 8	Annex II (excluding section 4)	61230	15766
6284741	LATERAL PORTS 7X14X11 SPACER	Apr-12	Rule 8	Annex II (excluding section 4)	61230	15766
6284841	LATERAL PORTS 8X14X11 SPACER	Apr-12	Rule 8	Annex II (excluding section 4)	61230	15766
6284941	LATERAL PORTS 9X14X11 SPACER	Apr-12	Rule 8	Annex II (excluding section 4)	61230	15766

Product List

Last updated by: Lila Joe
Tech File Bundle: Cervical Fusion, TF008

Date: 2/22/2021

Product: CORNERSTONE-SR™ Cage System (Implants)

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
621001404	Anatomical PEEK cage 14x11x4	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001405	Anatomical PEEK cage 14x11x5	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001406	Anatomical PEEK cage 14x11x6	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001407	Anatomical PEEK cage 14x11x7	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001408	Anatomical PEEK cage 14x11x8	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001409	Anatomical PEEK cage 14x11x9	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001604	Anatomical PEEK cage 16x14x4	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001605	Anatomical PEEK cage 16x14x5	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001606	Anatomical PEEK cage 16x14x6	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001607	Anatomical PEEK cage 16x14x7	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001804	Anatomical PEEK cage 18x16x4	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001805	Anatomical PEEK cage 18x16x5	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001806	Anatomical PEEK cage 18x16x6	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
621001807	Anatomical PEEK cage 18x16x7	Jun-13	Rule 8	Annex II (excluding section 4)	61230	15766
6211404	ANATOMICAL PEEK CAGE 14x11x4	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211405	ANATOMICAL PEEK CAGE 14x11x5	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211406	ANATOMICAL PEEK CAGE 14x11x6	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211407	ANATOMICAL PEEK CAGE 14x11x7	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211408	ANATOMICAL PEEK CAGE 14x11x8	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211409	ANATOMICAL PEEK CAGE 14x11x9	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211604	ANATOMICAL PEEK CAGE 16x14x4	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211605	ANATOMICAL PEEK CAGE 16x14x5	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211606	ANATOMICAL PEEK CAGE 16x14x6	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211607	ANATOMICAL PEEK CAGE 16x14x7	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211804	ANATOMICAL PEEK CAGE 18x16x4	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211805	ANATOMICAL PEEK CAGE 18x16x5	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211806	ANATOMICAL PEEK CAGE 18x16x6	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6211807	ANATOMICAL PEEK CAGE 18x16x7	Nov-11	Rule 8	Annex II (excluding section 4)	61230	15766
6271414	CRNRSTONE-SR PEEK CAGE 14X11X4	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6271415	CRNRSTONE-SR PEEK CAGE 14X11X5	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6271416	CRNRSTONE-SR PEEK CAGE 14X11X6	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6271417	CRNRSTONE-SR PEEK CAGE 14X11X7	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6271418	CRNRSTONE-SR PEEK CAGE 14X11X8	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6271419	CRNRSTONE-SR PEEK CAGE 14X11X9	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272414	CORN-SR PEEK ANAT CAGE 14X11X4	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272415	CORN-SR PEEK ANAT CAGE 14X11X5	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272416	CORN-SR PEEK ANAT CAGE 14X11X6	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272417	CORN-SR PEEK ANAT CAGE 14X11X7	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272418	CORN-SR PEEK ANAT CAGE 14X11X8	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272419	CORN-SR PEEK ANAT CAGE 14X11X9	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272744	CORN-SR PEEK ANAT CAGE 17X14X4	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272745	CORN-SR PEEK ANAT CAGE 17X14X5	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272746	CORN-SR PEEK ANAT CAGE 17X14X6	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272747	CORN-SR PEEK ANAT CAGE 17X14X7	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272748	CORN-SR PEEK ANAT CAGE 17X14X8	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766
6272749	CORN-SR PEEK ANAT CAGE 17X14X9	Jul-03	Rule 8	Annex II (excluding section 4)	61230	15766

Product List

Last updated by: Lila Joe
Tech File Bundle: Cervical Fusion, TF008

Date: 2/22/2021

Product: CORNERSTONE-SR™ Ti Coated Cage System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
6221404	Spacer 4mm x 14mm x 11mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221405	Spacer 5mm x 14mm x 11mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221406	Spacer 6mm x 14mm x 11mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221407	Spacer 7mm x 14mm x 11mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221408	Spacer 8mm x 14mm x 11mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221409	Spacer 9mm x 14mm x 11mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221604	Spacer 4mm x 16mm x 14mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221605	Spacer 5mm x 16mm x 14mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221606	Spacer 6mm x 16mm x 14mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221607	Spacer 7mm x 16mm x 14mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221804	Spacer 4mm x 18mm x 16mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221805	Spacer 5mm x 18mm x 16mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221806	Spacer 6mm x 18mm x 16mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766
6221807	Spacer 7mm x 18mm x 16mm	Jul-14	Rule 8	Annex II (excluding section 4)	61230	15766

Product List

Last updated by: Lila Joe
Tech File Bundle: Cervical Fusion, TF008

Date: 2/22/2021

Product: DIVERGENCE™ Anterior Cervical Fusion System
Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G7731505	Mini Plate, 15.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7731506	Mini Plate, 16.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7731507	Mini Plate, 17.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7731508	Mini Plate, 18.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7731509	Mini Plate, 19.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7731510	Mini Plate, 20.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7731511	Mini Plate, 21.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7731512	Mini Plate, 22.5mm	Jan-15	Rule 8	Annex II (excluding section 4)	46653	15766
G7733509	Self-Drilling Screw, 3.5mm x 9mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733510	Self-Drilling Screw, 3.5mm x 10mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733511	Self-Drilling Screw, 3.5mm x 11mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733512	Self-Drilling Screw, 3.5mm x 12mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733513	Self-Drilling Screw, 3.5mm x 13mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733514	Self-Drilling Screw, 3.5mm x 14mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733515	Self-Drilling Screw, 3.5mm x 15mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733516	Self-Drilling Screw, 3.5mm x 16mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733517	Self-Drilling Screw, 3.5mm x 17mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733518	Self-Drilling Screw, 3.5mm x 18mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733519	Self-Drilling Screw, 3.5mm x 19mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733520	Self-Drilling Screw, 3.5mm x 20mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733521	Self-Drilling Screw, 3.5mm x 21mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733522	Self-Drilling Screw, 3.5mm x 22mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733523	Self-Drilling Screw, 3.5mm x 23mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7733524	Self-Drilling Screw, 3.5mm x 24mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734009	Self-Drilling Screw, 4.0mm x 9mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734010	Self-Drilling Screw, 4.0mm x 10mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734011	Self-Drilling Screw, 4.0mm x 11mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734012	Self-Drilling Screw, 4.0mm x 12mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734013	Self-Drilling Screw, 4.0mm x 13mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734014	Self-Drilling Screw, 4.0mm x 14mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734015	Self-Drilling Screw, 4.0mm x 15mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734016	Self-Drilling Screw, 4.0mm x 16mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734017	Self-Drilling Screw, 4.0mm x 17mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734018	Self-Drilling Screw, 4.0mm x 18mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734019	Self-Drilling Screw, 4.0mm x 19mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734020	Self-Drilling Screw, 4.0mm x 20mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734021	Self-Drilling Screw, 4.0mm x 21mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734022	Self-Drilling Screw, 4.0mm x 22mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734023	Self-Drilling Screw, 4.0mm x 23mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7734024	Self-Drilling Screw, 4.0mm x 24mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743509	Self-Tapping Screw, 3.5mm x 9mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743510	Self-Tapping Screw, 3.5mm x 10mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743511	Self-Tapping Screw, 3.5mm x 11mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743512	Self-Tapping Screw, 3.5mm x 12mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743513	Self-Tapping Screw, 3.5mm x 13mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743514	Self-Tapping Screw, 3.5mm x 14mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743515	Self-Tapping Screw, 3.5mm x 15mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743516	Self-Tapping Screw, 3.5mm x 16mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743517	Self-Tapping Screw, 3.5mm x 17mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743518	Self-Tapping Screw, 3.5mm x 18mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743519	Self-Tapping Screw, 3.5mm x 19mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743520	Self-Tapping Screw, 3.5mm x 20mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743521	Self-Tapping Screw, 3.5mm x 21mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743522	Self-Tapping Screw, 3.5mm x 22mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743523	Self-Tapping Screw, 3.5mm x 23mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7743524	Self-Tapping Screw, 3.5mm x 24mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7744009	Self-Tapping Screw, 4.0mm x 9mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7744010	Self-Tapping Screw, 4.0mm x 10mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7744011	Self-Tapping Screw, 4.0mm x 11mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7744012	Self-Tapping Screw, 4.0mm x 12mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766
G7744013	Self-Tapping Screw, 4.0mm x 13mm	Jan-15	Rule 8	Annex II (excluding section 4)	46651	15766

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G6620549	Parallel Stand-Alone Interbody Cage, 15mm x 14mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620540	Parallel Stand-Alone Interbody Cage, 15mm x 14mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620541	Parallel Stand-Alone Interbody Cage, 15mm x 14mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620542	Parallel Stand-Alone Interbody Cage, 15mm x 14mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620745	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620746	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620747	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620748	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620749	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620740	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620741	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620742	Parallel Stand-Alone Interbody Cage, 17mm x 14mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620765	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620766	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620767	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620768	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620769	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620760	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620761	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620762	Parallel Stand-Alone Interbody Cage, 17mm x 16mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620245	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620246	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620247	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620248	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620249	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620240	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620241	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620242	Parallel Stand-Alone Interbody Cage, 20mm x 14mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620265	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620266	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620267	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620268	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620269	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G6620260	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620261	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6620262	Parallel Stand-Alone Interbody Cage, 20mm x 16mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626525	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626526	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626527	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626528	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626529	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626520	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626521	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626522	Lordotic Stand-Alone Interbody Cage, 15mm x 12mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626545	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626546	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626547	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626548	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626549	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 9mm	Mar-17	Rule 8	Annex II (excluding section 4)	61230	15766
G6626540	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626541	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626542	Lordotic Stand-Alone Interbody Cage, 15mm x 14mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626745	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626746	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626747	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626748	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626749	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626740	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626741	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626742	Lordotic Stand-Alone Interbody Cage, 17mm x 14mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626765	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626766	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626767	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626768	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626769	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626760	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G6626761	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626762	Lordotic Stand-Alone Interbody Cage, 17mm x 16mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626265	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 5mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626266	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 6mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626267	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 7mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626268	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 8mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626269	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626260	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626261	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6626262	Lordotic Stand-Alone Interbody Cage, 20mm x 16mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	61230	15766
G6623509	SA Self-Drilling Screw, 3.5mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6623510	SA Self-Drilling Screw, 3.5mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6623511	SA Self-Drilling Screw, 3.5mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6623512	SA Self-Drilling Screw, 3.5mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6623513	SA Self-Drilling Screw, 3.5mm x 13mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6623514	SA Self-Drilling Screw, 3.5mm x 14mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6623515	SA Self-Drilling Screw, 3.5mm x 15mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6623516	SA Self-Drilling Screw, 3.5mm x 16mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624009	SA Self-Drilling Screw, 4.0mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624010	SA Self-Drilling Screw, 4.0mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624011	SA Self-Drilling Screw, 4.0mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624012	SA Self-Drilling Screw, 4.0mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624013	SA Self-Drilling Screw, 4.0mm x 13mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624014	SA Self-Drilling Screw, 4.0mm x 14mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624015	SA Self-Drilling Screw, 4.0mm x 15mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624016	SA Self-Drilling Screw, 4.0mm x 16mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6624017	SA Self-Drilling Screw, 4.0mm x 17mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633509	SA Self-Tapping Screw, 3.5mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633510	SA Self-Tapping Screw, 3.5mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633511	SA Self-Tapping Screw, 3.5mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633512	SA Self-Tapping Screw, 3.5mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633513	SA Self-Tapping Screw, 3.5mm x 13mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633514	SA Self-Tapping Screw, 3.5mm x 14mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633515	SA Self-Tapping Screw, 3.5mm x 15mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633516	SA Self-Tapping Screw, 3.5mm x 16mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6633517	SA Self-Tapping Screw, 3.5mm x 17mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634009	SA Self-Tapping Screw, 4.0mm x 9mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634010	SA Self-Tapping Screw, 4.0mm x 10mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634011	SA Self-Tapping Screw, 4.0mm x 11mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634012	SA Self-Tapping Screw, 4.0mm x 12mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634013	SA Self-Tapping Screw, 4.0mm x 13mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634014	SA Self-Tapping Screw, 4.0mm x 14mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634015	SA Self-Tapping Screw, 4.0mm x 15mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634016	SA Self-Tapping Screw, 4.0mm x 16mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766
G6634017	SA Self-Tapping Screw, 4.0mm x 17mm	Jun-15	Rule 8	Annex II (excluding section 4)	46651	15766

Product List

Last updated by:	Lila Joe
Tech File Bundle:	Cervical Fusion, TF008

Date: 5/22/2020

Product:	VENTURE™					
Class:	IIB					
P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9790019	ANT. CERV. PLATE ASS'Y 19MM	Jul-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790021	ANT. CERV. PLATE ASS'Y 21MM	Jul-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790023	ANT. CERV. PLATE ASS'Y 23MM	Jul-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790025	ANT. CERV. PLATE ASS'Y 25MM	Jul-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790027	ANT. CERV. PLATE ASS'Y 27.5MM	Jul-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790030	ANT. CERV. PLATE ASS'Y 30MM	Jul-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790032	ANT. CERV. PLATE ASS'Y 32.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790035	ANT. CERV. PLATE ASS'Y 35MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790037	ANT. CERV. PLATE ASS'Y 37.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790040	ANT. CERV. PLATE ASS'Y 40MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790042	ANT. CERV. PLATE ASS'Y 42.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790045	ANT. CERV. PLATE ASS'Y 45MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790047	ANT. CERV. PLATE ASS'Y 47.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790050	ANT. CERV. PLATE ASS'Y 50MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790052	ANT. CERV. PLATE ASS'Y 52.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790055	ANT. CERV. PLATE ASS'Y 55MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790057	ANT. CERV. PLATE ASS'Y 57.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790060	ANT. CERV. PLATE ASS'Y 60MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790062	ANT. CERV. PLATE ASS'Y 62.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790065	ANT. CERV. PLATE ASS'Y 65MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790067	ANT. CERV. PLATE ASS'Y 67.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790070	ANT. CERV. PLATE ASS'Y 70MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790072	ANT. CERV. PLATE ASS'Y 72.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790075	ANT. CERV. PLATE ASS'Y 75MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790077	ANT. CERV. PLATE ASS'Y 77.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790080	ANT. CERV. PLATE ASS'Y 80MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790082	ANT. CERV. PLATE ASS'Y 82.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790085	ANT. CERV. PLATE ASS'Y 85MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790087	ANT. CERV. PLATE ASS'Y 87.5MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790090	ANT. CERV. PLATE ASS'Y 90MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790095	ANT. CERV. PLATE ASS'Y 95MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790100	ANT. CERV. PLATE ASS'Y 100MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790105	ANT. CERV. PLATE ASS'Y 105MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790110	ANT. CERV. PLATE ASS'Y 110MM	Aug-04	Rule 8	Annex II (excluding section 4)	46653	15766
9790211	4.0 X 11 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790213	4.0 X 13 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790215	4.0 X 15 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790217	4.0 X 17 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790219	4.0 X 19 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790311	4.0 X 11 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790313	4.0 X 13 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790315	4.0 X 15 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790317	4.0 X 17 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9790319	4.0 X 19 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9791030	ANT CER PLATE ASS'Y 30MM TRANS	Sep-04	Rule 8	Annex II (excluding section 4)	46653	15766
9791150	ANT CER PLATE ASS'Y 50MM TRANS	Sep-04	Rule 8	Annex II (excluding section 4)	46653	15766
9791221	4.0 X 11 SELF-DRILL FIX SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791223	4.0 X 13 SELF-DRILL FIX SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791224	4.0 X 14 SELF-DRILL FIX SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791225	4.0 X 15 SELF-DRILL FIX SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791227	4.0 X 17 SELF-DRILL FIX SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791321	4.0 X 11 SELF-DRILL VAR SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791323	4.0 X 13 SELF-DRILL VAR SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791324	4.0 X 14 SELF-DRILL VAR SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791325	4.0 X 15 SELF-DRILL VAR SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9791327	4.0 X 17 SELF-DRILL VAR SCREW	Sep-05	Rule 8	Annex II (excluding section 4)	61325	15766
9795211	4.5 X 11 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795213	4.5 X 13 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795215	4.5 X 15 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795217	4.5 X 17 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795219	4.5 X 19 SELF-TAP FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795221	4.5 X 11 SELF-DRILL FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795223	4.5 X 13 SELF-DRILL FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795225	4.5 X 15 SELF-DRILL FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795227	4.5 X 17 SELF-DRILL FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795229	4.5 X 19 SELF-DRILL FIX SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795311	4.5 X 11 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795313	4.5 X 13 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795315	4.5 X 15 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795317	4.5 X 17 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795319	4.5 X 19 SELF-TAP VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795321	4.5 X 11 SELF-DRILL VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
9795323	4.5 X 13 SELF-DRILL VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795325	4.5 X 15 SELF-DRILL VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795327	4.5 X 17 SELF-DRILL VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
9795329	4.5 X 19 SELF-DRILL VAR SCREW	Aug-04	Rule 8	Annex II (excluding section 4)	61325	15766
G9790019	ANT CERV PLATE ASS'Y 19MM, STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790021	ANT CER PLATE ASS'Y 21MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790023	ANT CER PLATE ASS'Y 23MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790025	ANT CER PLATE ASS'Y 25MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790027	ANT CER PLATE ASS'Y 27.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790030	ANT CER PLATE ASS'Y 30MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790032	ANT CER PLATE ASS'Y 32.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790035	ANT CER PLATE ASS'Y 35MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790037	ANT CER PLATE ASS'Y 37.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790040	ANT CER PLATE ASS'Y 40MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790042	ANT CER PLATE ASS'Y 42.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790045	ANT CERV PLATE ASS'Y 45MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790047	ANT CER PLATE ASS'Y 47.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790050	ANT CER PLATE ASS'Y 50MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790052	ANT CER PLATE ASS'Y 52.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790055	ANT CER PLATE ASS'Y 55MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790057	ANT CER PLATE ASS'Y 57.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790060	ANT CER PLATE ASS'Y 60MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790062	ANT CER PLATE ASS'Y 62.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790065	ANT CER PLATE ASS'Y 65MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790067	ANT CER PLATE ASS'Y 67.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790070	ANT CER PLATE ASS'Y 70MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790072	ANT CER PLATE ASS'Y 72.5MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790075	ANT CER PLATE ASS'Y 75MM,STERILE	May-06	Rule 8	Annex II (excluding section 4)	46653	15766
G9790211	4.0 X 11 SELF-TAP FIX SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9790213	4.0 X 13 SELF-TAP FIX SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9790215	4.0 X 15 SELF-TAP FIX SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9790311	4.0 X 11 SELF-TAP VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9790313	4.0 X 13 SELF-TAP VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9790315	4.0 X 15 SELF-TAP VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9790317	4.0 X 17 SELF-TAP VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9790319	4.0 X 19 SELF-TAP VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9791223	4.0 X 13 SELF-DRILL FIX SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9791225	4.0 X 15 SELF-DRILL FIX SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9791323	4.0 X 13 SELF-DRILL VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9791325	4.0 X 15 SELF-DRILL VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9795213	4.5 X 13 SELF-TAP FIX SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9795215	4.5 X 15 SELF-TAP FIX SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9795313	4.5 X 13 SELF-TAP VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766
G9795315	4.5 X 15 SELF-TAP VAR SCREW, STERILE	Apr-06	Rule 8	Annex II (excluding section 4)	46651	15766

Product List

Last updated by: Lila Joe
Tech File Bundle: Cervical Fusion, TF008

Date: 5/22/2020

Product: ZEVO™ Anterior Cervical Plate System

Class: IIb

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
3001015	1 level, LP ACP, 15mm	Feb-16	Rule 8	Annex II (-section 4)	46653	15766
3001017	1 level, LP ACP, 17mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3001019	1 level, LP ACP, 19mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3001021	1 level, LP ACP, 21mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3001023	1 level, LP ACP, 23mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3001025	1 level, LP ACP, 25mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3001027	1 level, LP ACP, 27mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3001029	1 level, LP ACP, 29mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3001031	1 level, LP ACP, 31mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002027	2 level, LP ACP, 27mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002029	2 level, LP ACP, 29mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002031	2 level, LP ACP, 31mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002033	2 level, LP ACP, 33mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002035	2 level, LP ACP, 35mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002037	2 level, LP ACP, 37mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002039	2 level, LP ACP, 39mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002041	2 level, LP ACP, 41mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002043	2 level, LP ACP, 43mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002045	2 level, LP ACP, 45mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002047	2 level, LP ACP, 47mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002048	2 level, LP ACP, 48mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002049	2 level, LP ACP, 49mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002051	2 level, LP ACP, 51mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3002053	2 level, LP ACP, 53mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003043	3 level, LP ACP, 43mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003045	3 level, LP ACP, 45mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003047	3 level, LP ACP, 47mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003048	3 level, LP ACP, 48mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003049	3 level, LP ACP, 49mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003051	3 level, LP ACP, 51mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003053	3 level, LP ACP, 53mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003055	3 level, LP ACP, 55mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003057	3 level, LP ACP, 57mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003059	3 level, LP ACP, 59mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003061	3 level, LP ACP, 61mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003063	3 level, LP ACP, 63mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003065	3 level, LP ACP, 65mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003067	3 level, LP ACP, 67mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003068	3 level, LP ACP, 68mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003069	3 level, LP ACP, 69mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3003071	3 level, LP ACP, 71mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004065	4 level, LP ACP, 65mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004067	4 level, LP ACP, 67mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004069	4 level, LP ACP, 69mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004071	4 level, LP ACP, 71mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004073	4 level, LP ACP, 73mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004075	4 level, LP ACP, 75mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004077	4 level, LP ACP, 77mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004078	4 level, LP ACP, 78mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004079	4 level, LP ACP, 79mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004081	4 level, LP ACP, 81mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004083	4 level, LP ACP, 83mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004085	4 level, LP ACP, 85mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004086	4 level, LP ACP, 86mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004087	4 level, LP ACP, 87mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3004089	4 level, LP ACP, 89mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3005075	5 level, LP ACP, 75mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3005077	5 level, LP ACP, 77mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3005079	5 level, LP ACP, 79mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
3005081	5 level, LP ACP, 81mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
7724023	SCREW ZEVO VAR ST 4.0MM X 23MM	Jun-15	Rule 8	Annex II (-section 4)	61325	15766
7724024	SCREW ZEVO VAR ST 4.0MM X 24MM	Jun-15	Rule 8	Annex II (-section 4)	61325	15766
G3001015	1 level, LP ACP, 15mm	Feb-16	Rule 8	Annex II (-section 4)	46653	15766
G3001017	1 level, LP ACP, 17mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3001019	1 level, LP ACP, 19mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3001021	1 level, LP ACP, 21mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3001023	1 level, LP ACP, 23mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3001025	1 level, LP ACP, 25mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3001027	1 level, LP ACP, 27mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3001029	1 level, LP ACP, 29mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3001031	1 level, LP ACP, 31mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002027	2 level, LP ACP, 27mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002029	2 level, LP ACP, 29mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002031	2 level, LP ACP, 31mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002033	2 level, LP ACP, 33mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002035	2 level, LP ACP, 35mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002037	2 level, LP ACP, 37mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002039	2 level, LP ACP, 39mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002041	2 level, LP ACP, 41mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002043	2 level, LP ACP, 43mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002045	2 level, LP ACP, 45mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002047	2 level, LP ACP, 47mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002048	2 level, LP ACP, 48mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002049	2 level, LP ACP, 49mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002051	2 level, LP ACP, 51mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3002053	2 level, LP ACP, 53mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003043	3 level, LP ACP, 43mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003045	3 level, LP ACP, 45mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003047	3 level, LP ACP, 47mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003048	3 level, LP ACP, 48mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003049	3 level, LP ACP, 49mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003051	3 level, LP ACP, 51mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003053	3 level, LP ACP, 53mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003055	3 level, LP ACP, 55mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003057	3 level, LP ACP, 57mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003059	3 level, LP ACP, 59mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003061	3 level, LP ACP, 61mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003063	3 level, LP ACP, 63mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003065	3 level, LP ACP, 65mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003067	3 level, LP ACP, 67mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003068	3 level, LP ACP, 68mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003069	3 level, LP ACP, 69mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3003071	3 level, LP ACP, 71mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004065	4 level, LP ACP, 65mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004067	4 level, LP ACP, 67mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004069	4 level, LP ACP, 69mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004071	4 level, LP ACP, 71mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004073	4 level, LP ACP, 73mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004075	4 level, LP ACP, 75mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004077	4 level, LP ACP, 77mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004078	4 level, LP ACP, 78mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004079	4 level, LP ACP, 79mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004081	4 level, LP ACP, 81mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004083	4 level, LP ACP, 83mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004085	4 level, LP ACP, 85mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004086	4 level, LP ACP, 86mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004087	4 level, LP ACP, 87mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3004089	4 level, LP ACP, 89mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005075	5 level, LP ACP, 75mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005077	5 level, LP ACP, 77mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005079	5 level, LP ACP, 79mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005081	5 level, LP ACP, 81mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005085	5 level, LP ACP, 85mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005090	5 level, LP ACP, 90mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005095	5 level, LP ACP, 95mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766
G3005100	5 level, LP ACP, 100mm	Jun-15	Rule 8	Annex II (-section 4)	46653	15766

P/N	DESCRIPTION	INITIAL DATE OF CE MARKING	RULE	CONFORMANCE PATHWAY	GMDN	UMDNS
G7724012	SCREW ZEVO VAR ST 4.0MM X 12MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724013	SCREW ZEVO VAR ST 4.0MM X 13MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724014	SCREW ZEVO VAR ST 4.0MM X 14MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724015	SCREW ZEVO VAR ST 4.0MM X 15MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724016	SCREW ZEVO VAR ST 4.0MM X 16MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724017	SCREW ZEVO VAR ST 4.0MM X 17MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724018	SCREW ZEVO VAR ST 4.0MM X 18MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724019	SCREW ZEVO VAR ST 4.0MM X 19MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724020	SCREW ZEVO VAR ST 4.0MM X 20MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724021	SCREW ZEVO VAR ST 4.0MM X 21MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724022	SCREW ZEVO VAR ST 4.0MM X 22MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724023	SCREW ZEVO VAR ST 4.0MM X 23MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7724024	SCREW ZEVO VAR ST 4.0MM X 24MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783510	SCREW ZEVO VAR ST, 3.5MM X 10MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783511	SCREW ZEVO VAR ST, 3.5MM X 11MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783512	SCREW ZEVO VAR ST, 3.5MM X 12MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783513	SCREW ZEVO VAR ST, 3.5MM X 13MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783514	SCREW ZEVO VAR ST, 3.5MM X 14MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783515	SCREW ZEVO VAR ST, 3.5MM X 15MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783516	SCREW ZEVO VAR ST, 3.5MM X 16MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783517	SCREW ZEVO VAR ST, 3.5MM X 17MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783518	SCREW ZEVO VAR ST, 3.5MM X 18MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783519	SCREW ZEVO VAR ST, 3.5MM X 19MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783520	SCREW ZEVO VAR ST, 3.5MM X 20MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783521	SCREW ZEVO VAR ST, 3.5MM X 21MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783522	SCREW ZEVO VAR ST, 3.5MM X 22MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783523	SCREW ZEVO VAR ST, 3.5MM X 23MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766
G7783524	SCREW ZEVO VAR ST, 3.5MM X 24MM	Jun-15	Rule 8	Annex II (-section 4)	46651	15766



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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 039040 0078 Rev. 00

Manufacturer:

**Medtronic Sofamor Danek
USA, Inc.**

1800 Pyramid Place
Memphis, TN 38132
USA

Product Category(ies):

**Synthetic Bone Graft combined with Biological
Origin, Bone Cement, Kyphoplasty Devices, Bone
Tamps, Bone Filler Devices, Osteo Introducer
Kits, Bone Biopsy Devices, Inflation
Syringes, Spinal, Cranial, Dental, and Orthopedic
Implants, Sterile Spinal Implants, Sterile Synthetic
Bone Substitutes, Sterile Instruments, Cutters,
Retractors, Electrical Drive Systems, Electrosurgical
Instruments, Endoscopes, Neurological Electrodes,
Radio-Frequency Ablation System Generators,
Radio Frequency Ablation Systems Including Sterile
Probes, Tubing Kits, Pumps, Connectors
and Cannulas/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.:

72154162

Valid from:

2020-04-27

Valid until:

2024-05-26

Date,

2020-04-27

Christoph Dicks
Head of Certification/Notified Body