



DEKLARACJA ZGODNOŚCI

Dyrektywa Rady 93/42/EWG dotycząca wyrobów medycznych

Wytwórca: **T.A.G. MEDICAL PRODUCTS CORPORATION LTD.**
Kibbutz Gaaton 2513000 Izrael
Tel: (972) 4 9858400
Fax: (972) 4 9858404
E-mail: tagltd@netvision.net.il

Autoryzowany
Przedstawiciel: **MedNet EC-REP GmbH**
Borkstrasse 10
48163 Munster, Niemcy
Phone: +49 251 32266-0

Ja, niżej podpisany, niniejszym oświadczam, że dystrybuowane produkty z oznaczeniem CE wyszczególnione na załączonej liście produktów, są produktami objętymi „Certyfikatem zgodności z oznakowaniem CE” o numerze referencyjnym 32655-22 i dokumentem uzupełniającym o numerze 37072 Rev.8, wydanym przez Jednostkę Notyfikowaną GMED, 1, rue Gaston Boissier, 75015 Paryż, Francja, o numerze identyfikacyjnym 0459, zgodnie z Załącznikiem II do Dyrektywy Rady 93/42/EWG z dnia 14 czerwca 1993 r. dotyczącej wyrobów medycznych.


Niniejszej deklaracji zgodności towarzyszy certyfikat Systemu Zarządzania Jakością dla przedmiotowych produktów, zgodnie z Załącznikiem II do Dyrektywy WE. System zarządzania jakością jest zgodny z ISO 13485:2016, i poparty Certyfikatem Zgodności o numerze 32657, wydanym i dostarczonym przez GMED, 1, rue Gaston Boissier, 75015 Paryż, Francja.

Miejsce i data wydania: Gaaton, 9 maja 2024 r.

Podpis:

Imię i nazwisko:

Stanowisko


Hagay Sitry
Dyrektor Generalny

Certyfikat jest ważny do 31-gru-2027

Załącznik – wykaz produktów

Niniejszy wykaz produktów towarzyszy Deklaracji Zgodności T.A.G. Medical Products i dotyczy produktów oznaczonych znakiem CE, które T.A.G. Medical Products zamierza dystrybuować zgodnie z postanowieniami Dyrektywy Rady 93/42/EWG z dnia 14 czerwca 1993 roku dotyczącej wyrobów medycznych.

Poniższy wykaz identyfikuje produkty według numeru modelu i typu.

Kategoria: Wszczepialne urządzenia do mocowania kości

Kod GMDN: 36174

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
la523st20	la523st20m	Latarjet Cortical Screw Set 20 SS	Rule 8 - IIb	Jul-2011
la523st22	la523st22m	Latarjet Cortical Screw Set 22 SS	Rule 8 - IIb	Jul-2011
la523st24	la523st24m	Latarjet Cortical Screw Set 24 SS	Rule 8 - IIb	Jul-2011
la523st26	la523st26m	Latarjet Cortical Screw Set 26 SS	Rule 8 - IIb	Jul-2011
la523st28	la523st28m	Latarjet Cortical Screw Set 28 SS	Rule 8 - IIb	Jul-2011
la523st30	la523st30m	Latarjet Cortical Screw Set 30 SS	Rule 8 - IIb	Jul-2011
la523st32	la523st32m	Latarjet Cortical Screw Set 32 SS	Rule 8 - IIb	Jul-2011
la523st34	la523st34m	Latarjet Cortical Screw Set 34 SS	Rule 8 - IIb	Jul-2011
la523st36	la523st36m	Latarjet Cortical Screw Set 36 SS	Rule 8 - IIb	Nov-2008
la523st38	la523st38m	Latarjet Cortical Screw Set 38 SS	Rule 8 - IIb	Nov-2008
la523st40	la523st40m	Latarjet Cortical Screw Set 40 SS	Rule 8 - IIb	Nov-2008
la523st42	la523st42m	Latarjet Cortical Screw Set 42 SS	Rule 8 - IIb	Nov-2008
la523st44	la523st44m	Latarjet Cortical Screw Set 44 SS	Rule 8 - IIb	Jun-2009
la523st46	la523st46m	Latarjet Cortical Screw Set 46 SS	Rule 8 - IIb	Jun-2009
la523st48	la523st48m	Latarjet Cortical Screw Set 48 SS	Rule 8 - IIb	Jun-2009
la52320	la52320m	Latarjet Cortical Screw Set 20 Ti	Rule 8 - IIb	Jul-2011
la52322	la52322m	Latarjet Cortical Screw Set 22 Ti	Rule 8 - IIb	Jul-2011
la52324	la52324m	Latarjet Cortical Screw Set 24 Ti	Rule 8 - IIb	Jul-2011
la52326	la52326m	Latarjet Cortical Screw Set 26 Ti	Rule 8 - IIb	Jul-2011
la52328	la52328m	Latarjet Cortical Screw Set 28 Ti	Rule 8 - IIb	Jul-2011
la52330	la52330m	Latarjet Cortical Screw Set 30 Ti	Rule 8 - IIb	Jul-2011
la52332	la52332m	Latarjet Cortical Screw Set 32 Ti	Rule 8 - IIb	Jul-2011
la52334	la52334m	Latarjet Cortical Screw Set 34 Ti	Rule 8 - IIb	Jul-2011
la52336	la52336m	Latarjet Cortical Screw Set 36 Ti	Rule 8 - IIb	Nov-2008
la52338	la52338m	Latarjet Cortical Screw Set 38 Ti	Rule 8 - IIb	Nov-2008
la52340	la52340m	Latarjet Cortical Screw Set 40 Ti	Rule 8 - IIb	Nov-2008
la52342	la52342m	Latarjet Cortical Screw Set 42 Ti	Rule 8 - IIb	Nov-2008

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
la52344	la52344m	Latarjet Cortical Screw Set 44 Ti	Rule 8 - IIb	Jun-2009
la52346	la52346m	Latarjet Cortical Screw Set 46 Ti	Rule 8 - IIb	Jun-2009
la52348	la52348m	Latarjet Cortical Screw Set 48 Ti	Rule 8 - IIb	Jun-2009

Kategoria: Zestaw jednorazowy Latarjet

Kod GMDN: 44093

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
285180	la523dis-setm	Latarjet Disposable Kit	Rule 6 - IIa	Jul-2010
285200	la523bdis-setm	Bristow Disposable Kit	Rule 6 - IIa	Jul-2010

Kategoria: Przeciągacz szwów

Kod GMDN: 57874

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
251001	251001m	Suture Shuttle 25° Left	Rule 6 - IIa	Jan-2009
251002	251002m	Suture Shuttle 25° Right	Rule 6 - IIa	Jan-2009
251003	251003m	Suture Shuttle 45° Left	Rule 6 - IIa	Jan-2009
251004	251004m	Suture Shuttle 45° Right	Rule 6 - IIa	Jan-2009
251005	251005m	Suture Shuttle 90° Up	Rule 6 - IIa	Jan-2009
251006	251006m	Suture Shuttle Straight Hook	Rule 6 - IIa	Jan-2009
251007	251007m	Suture Shuttle Str. Crescent	Rule 6 - IIa	Jan-2009

Kategoria: ArthroTunneler™

Kod GMDN: 44093

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
SMB000101	at555000tr	ArthroTunneler Device	Rule 6 - IIa	Dec-2009

Kategoria: System elastycznego rozwiertaka

Kod GMDN: 47138, 57789

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
234-108-020	tg108020st	Flexible Guide Pin	Rule 6 - IIa	Dec-2009
234-108-200	tg108200st	VersiTomic® Flexible Guide pin (Flexible Guide Pin)	Rule 6 - IIa	Mar-2013
AR-1400FLX	109120s0ar	Flexible Guide Pin for Arthrex® Flexible Reamer	Rule 6 - IIa	Mar-2017
AR-1400F-70	109070ar	Arthrex® Flexible Reamer with Flexible Guide Pin 7 mm	Rule 6 - IIa	Mar-2017
AR-1400F-75	109075ar	Arthrex® Flexible Reamer with Flexible Guide Pin 7.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-80	109080ar	Arthrex® Flexible Reamer with Flexible Guide Pin 8 mm	Rule 6 - IIa	Mar-2017
AR-1400F-85	109085ar	Arthrex® Flexible Reamer with Flexible Guide Pin 8.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-90	109090ar	Arthrex® Flexible Reamer with Flexible Guide Pin 9 mm	Rule 6 - IIa	Mar-2017
AR-1400F-95	109095ar	Arthrex® Flexible Reamer with Flexible Guide Pin 9.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-100	109100ar	Arthrex® Flexible Reamer with Flexible Guide Pin 10 mm	Rule 6 - IIa	Mar-2017
AR-1400F-105	109105ar	Arthrex® Flexible Reamer with Flexible Guide Pin 10.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-110	109110ar	Arthrex® Flexible Reamer with Flexible Guide Pin 11 mm	Rule 6 - IIa	Mar-2017
AR-1400F-115	109115ar	Arthrex® Flexible Reamer with Flexible Guide Pin 11.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-120	109120ar	Arthrex® Flexible Reamer with Flexible Guide Pin 12 mm	Rule 6 - IIa	Mar-2017
AR-1401F-70	114070ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 7mm	Rule 6 - IIa	Apr-2018
AR-1401F-75	114075ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 7.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-80	114080ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 8mm	Rule 6 - IIa	Apr-2018
AR-1401F-85	114085ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 8.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-90	114090ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 9mm	Rule 6 - IIa	Apr-2018
AR-1401F-95	114095ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 9.5mm	Rule 6 - IIa	Apr-2018



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AR-1401F-100	1140100ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 10mm	Rule 6 - IIa	Apr-2018
AR-1401F-105	1140105ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 10.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-110	1140110ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 11mm	Rule 6 - IIa	Apr-2018
AR-1401F-115	1140115ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 11.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-120	1140120ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 12mm	Rule 6 - IIa	Apr-2018

Kategoria: Urządzenia do mocowania zawieszania**Kod GMDN: 36174**

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
234-100-000	tg100000st	G-Lok® with No Loop	Rule 8 -IIb	Jul-2011
234-101-015	tg101015st	G-Lok® with 15mm Loop	Rule 8 -IIb	Jul-2011
234-101-020	tg101020st	G-Lok® with 20mm Loop	Rule 8 -IIb	Jul-2011
234-101-025	tg101025st	G-Lok® with 25mm Loop	Rule 8 -IIb	Jul-2011
234-101-030	tg101030st	G-Lok® with 30mm Loop	Rule 8 -IIb	Jul-2011
234-101-035	tg101035st	G-Lok® with 35mm Loop	Rule 8 -IIb	Jul-2011
234-101-040	tg101040st	G-Lok® with 40mm Loop	Rule 8 -IIb	Jul-2011
234-101-045	tg101045st	G-Lok® with 45mm Loop	Rule 8 -IIb	Jul-2011
234-101-050	tg101050st	G-Lok® with 50mm Loop	Rule 8 -IIb	Jul-2011
234-100-016	tg100016st	G-Lok® XL	Rule 8 -IIb	Jul-2011

Kategoria: System kotwic Knotilus™**Kod GMDN: 45062**

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
3910-500-100	500100st	Knotilus™ Anchor, 3.5mm	Rule 8 -IIb	Mar-2012
3910-500-107	500107st	Knotilus™ Implant Loop, 25 mm	Rule 8 -IIb	Mar-2012

Kategoria: System ArthroTunneler™ TunnelPro™
Kod GMDN: 44093

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
SMB100101	at555010tr	ArthroTunneler™ TunnelPro™ System	Rule 8 -IIb	May-2012

Kategoria: System suwaków Champion®
Kod GMDN: 57874

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
3910-500-750	500750st	Champion® Slider Handle	Rule 6 - IIa	Apr-2013
3910-500-751	500751st	Slider Needle 45° Right	Rule 6 - IIa	Apr-2013
3910-500-752	500752st	Slider Needle 45° Left	Rule 6 - IIa	Apr-2013
3910-500-753	500753st	Slider Needle 25° Right	Rule 6 - IIa	Apr-2013
3910-500-754	500754st	Slider Needle 25° Left	Rule 6 - IIa	Apr-2013
3910-500-755	500755st	Slider Needle Crescent Large	Rule 6 - IIa	Apr-2013
3910-500-756	500756st	Slider Needle Crescent Medium	Rule 6 - IIa	Apr-2013
3910-500-757	500757st	Slider Needle 30° Straight	Rule 6 - IIa	Apr-2013
3910-500-758	500758st	Slider Needle 60° Straight	Rule 6 - IIa	Apr-2013
3910-500-759	500759st	Slider Needle Crescent Large XL	Rule 6 - IIa	Apr-2013
3910-500-760	500760st	Slider Needle Crescent Medium XL	Rule 6 - IIa	Apr-2013
3910-500-761	500761st	Slider Nitinol Shuttle	Rule 6 - IIa	Apr-2013
11457	500750p	Anika Suture Passer Handle	Rule 2 - IIa	Apr-2021
11458	500751p	Anika Suture Passer 45° Right Needle	Rule 6 - IIa	Apr-2021
11459	500752p	Anika Suture Passer 45° Left Needle	Rule 6 - IIa	Apr-2021
11460	500753p	Anika Suture Passer 25° Right Needle	Rule 6 - IIa	Apr-2021
11461	500754p	Anika Suture Passer 25° Left Needle	Rule 6 - IIa	Apr-2021
11462	500755p	Anika Suture Passer Crescent Large Needle	Rule 6 - IIa	Apr-2021
11463	500756p	Anika Suture Passer Crescent Mid Needle	Rule 6 - IIa	Apr-2021
11464	500757p	Anika Suture Passer Str Hook 30° Needle	Rule 6 - IIa	Apr-2021
11465	500758p	Anika Suture Passer Str Hook 60° Needle	Rule 6 - IIa	Apr-2021
11466	500759p	Anika Suture Passer Crescent Hip Large Needle	Rule 6 - IIa	Apr-2021
11467	500760p	Anika Suture Passer Crescent Hip Mid Needle	Rule 6 - IIa	Apr-2021
S36-5011-T	500750su	Slider Handle	Rule 2 - IIa	Apr-2021



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Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
S36-5012-T	500751su	Slider 45° Right Needle	Rule 6 - IIa	Apr-2021
S36-5013-T	500752su	Slider 45° Left Needle	Rule 6 - IIa	Apr-2021
S36-5014-T	500753su	Slider 25° Right Needle	Rule 6 - IIa	Apr-2021
S36-5015-T	500754su	Slider 25° Left Needle	Rule 6 - IIa	Apr-2021
S36-5016-T	500755su	Slider Crescent Large Needle	Rule 6 - IIa	Apr-2021
S36-5018-T	500756su	Slider Crescent Mid Needle	Rule 6 - IIa	Apr-2021
S36-5019-T	500757su	Slider Str Hook 30° Needle	Rule 6 - IIa	Apr-2021
S36-5020-T	500758su	Slider Str Hook 60° Needle	Rule 6 - IIa	Apr-2021
S36-5021-T	500759su	Slider Crescent Hip Large Needle	Rule 6 - IIa	Apr-2021
S36-5022-T	500760su	Slider Crescent Hip Mid Needle	Rule 6 - IIa	Apr-2021
S36-5023-T	146100su	Nitinol Loop Passer	Rule 6 - IIa	Apr-2021
110045841	500750bsm	Suture Passer Handle	Rule 2 - IIa	Apr-2021
110045842	500751bsm	Suture Passer Needle 45° RIGHT	Rule 6 - IIa	Apr-2021
110045843	500752bsm	Suture Passer Needle 45° LEFT	Rule 6 - IIa	Apr-2021
110045844	500753bsm	Suture Passer Needle 25° RIGHT	Rule 6 - IIa	Apr-2021
110045845	500754bsm	Suture Passer Needle 25° LEFT	Rule 6 - IIa	Apr-2021
110045846	500755bsm	Suture Passer Needle LRG CRESCENT	Rule 6 - IIa	Apr-2021
110045847	500756bsm	Suture Passer Needle MID CRESCENT	Rule 6 - IIa	Apr-2021
110045848	500757bsm	Suture Passer Needle 30° UP	Rule 6 - IIa	Apr-2021
110045849	500758bsm	Suture Passer Needle 60° UP	Rule 6 - IIa	Apr-2021
110045850	500759bsm	Suture Passer Needle HIP LRG CRESCENT	Rule 6 - IIa	Apr-2021
110045851	500760bsm	Suture Passer Needle HIP MID CRESCENT	Rule 6 - IIa	Apr-2021
---	500750t	Slider Handle	Rule 2 - IIa	Apr-2021
---	500751t	Slider 45° Right Needle	Rule 6 - IIa	Apr-2021
---	500752t	Slider 45° Left Needle	Rule 6 - IIa	Apr-2021
---	500753t	Slider 25° Right Needle	Rule 6 - IIa	Apr-2021
---	500754t	Slider 25° Left Needle	Rule 6 - IIa	Apr-2021
---	500755t	Slider Crescent Large Needle	Rule 6 - IIa	Apr-2021
---	500756t	Slider Crescent Mid Needle	Rule 6 - IIa	Apr-2021
---	500757t	Slider Str Hook 30° Needle	Rule 6 - IIa	Apr-2021
---	500758t	Slider Str Hook 60° Needle	Rule 6 - IIa	Apr-2021
---	500759t	Slider Crescent Hip Large Needle	Rule 6 - IIa	Apr-2021
---	500760t	Slider Crescent Hip Mid Needle	Rule 6 - IIa	Apr-2021

Kategoria: Instrumenty jednorazowe SwitchCut

Kod GMDN: 61235, 57874

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
110026885	145060bsm	SwitchCut Reamer 4.5 x 6.0mm	Rule 6 - IIa	Jan-2015
110026886	145065bsm	SwitchCut Reamer 4.5 x 6.5mm	Rule 6 - IIa	Jan-2015
110026887	145070bsm	SwitchCut Reamer 4.5 x 7.0mm	Rule 6 - IIa	Jan-2015
110026888	145075bsm	SwitchCut Reamer 4.5 x 7.5mm	Rule 6 - IIa	Jan-2015
110026889	145080bsm	SwitchCut Reamer 4.5 x 8.0mm	Rule 6 - IIa	Jan-2015
110026890	145085bsm	SwitchCut Reamer 4.5 x 8.5mm	Rule 6 - IIa	Jan-2015
110026891	145090bsm	SwitchCut Reamer 4.5 x 9.0mm	Rule 6 - IIa	Jan-2015
110026892	145095bsm	SwitchCut Reamer 4.5 x 9.5mm	Rule 6 - IIa	Jan-2015
110026893	145100bsm	SwitchCut Reamer 4.5 x 10.0mm	Rule 6 - IIa	Jan-2015
110026894	160105bsm	SwitchCut Reamer 6.0 x 10.5mm	Rule 6 - IIa	Jan-2015
110026895	160110bsm	SwitchCut Reamer 6.0 x 11.0mm	Rule 6 - IIa	Jan-2015
110026896	160115bsm	SwitchCut Reamer 6.0 x 11.5mm	Rule 6 - IIa	Jan-2015
110026897	160120bsm	SwitchCut Reamer 6.0 x 12.0mm	Rule 6 - IIa	Jan-2015
110026884	146000bsm	Nitinol Loop Passer	Rule 6 - IIa	Jan-2015
110027674	147060bsm	SwitchCut Reamer 4.5 x 6.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027675	147065bsm	SwitchCut Reamer 4.5 x 6.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027676	147070bsm	SwitchCut Reamer 4.5 x 7.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027677	147075bsm	SwitchCut Reamer 4.5 x 7.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027678	147080bsm	SwitchCut Reamer 4.5 x 8.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027679	147085bsm	SwitchCut Reamer 4.5 x 8.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027680	147090bsm	SwitchCut Reamer 4.5 x 9.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027681	147095bsm	SwitchCut Reamer 4.5 x 9.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027682	147100bsm	SwitchCut Reamer 4.5 x 10.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027683	161105bsm	SwitchCut Reamer 6.0 x 10.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027684	161110bsm	SwitchCut Reamer 6.0 x 11.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027685	161115bsm	SwitchCut Reamer 6.0 x 11.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
110027686	161120bsm	SwitchCut Reamer 6.0 x 12.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
0234-109-060	145060st	Retrograde Reamer 4.5 x 6.0mm	Rule 6 - IIa	Nov-2019
0234-109-065	145065st	Retrograde Reamer 4.5 x 6.5mm	Rule 6 - IIa	Nov-2019
0234-109-070	145070st	Retrograde Reamer 4.5 x 7.0mm	Rule 6 - IIa	Nov-2019
0234-109-075	145075st	Retrograde Reamer 4.5 x 7.5mm	Rule 6 - IIa	Nov-2019
0234-109-080	145080st	Retrograde Reamer 4.5 x 8.0mm	Rule 6 - IIa	Nov-2019
0234-109-085	145085st	Retrograde Reamer 4.5 x 8.5mm	Rule 6 - IIa	Nov-2019
0234-109-090	145090st	Retrograde Reamer 4.5 x 9.0mm	Rule 6 - IIa	Nov-2019
0234-109-095	145095st	Retrograde Reamer 4.5 x 9.5mm	Rule 6 - IIa	Nov-2019
0234-109-110	145100st	Retrograde Reamer 4.5 x 10.0mm	Rule 6 - IIa	Nov-2019
0234-109-111	145110st	Retrograde Reamer 6.0 x 11.0mm	Rule 6 - IIa	Nov-2019
0234-109-112	145120st	Retrograde Reamer 6.0 x 12.0mm	Rule 6 - IIa	Nov-2019
0234-109-005	146000st	Nitinol Wires	Rule 6 - IIa	Nov-2019
11469	145060p	Anika Retro Reamer 4.5 x 6mm	Rule 6 - IIa	Apr-2021
11470	145065p	Anika Retro Reamer 4.5 x 6.5mm	Rule 6 - IIa	Apr-2021
11471	145070p	Anika Retro Reamer 4.5 x 7mm	Rule 6 - IIa	Apr-2021
11472	145075p	Anika Retro Reamer 4.5 x 7.5mm	Rule 6 - IIa	Apr-2021
11473	145080p	Anika Retro Reamer 4.5 x 8mm	Rule 6 - IIa	Apr-2021
11474	145085p	Anika Retro Reamer 4.5 x 8.5mm	Rule 6 - IIa	Apr-2021
11475	145090p	Anika Retro Reamer 4.5 x 9mm	Rule 6 - IIa	Apr-2021
11476	145095p	Anika Retro Reamer 4.5 x 9.5mm	Rule 6 - IIa	Apr-2021
11477	145100p	Anika Retro Reamer 4.5 x 10mm	Rule 6 - IIa	Apr-2021
11478	160110p	Anika Retro Reamer 6 x 11mm	Rule 6 - IIa	Apr-2021
11479	160120p	Anika Retro Reamer 6 x 12mm	Rule 6 - IIa	Apr-2021
11468	146000p	Anika Suture Passer Shuttle (Nitinol)	Rule 6 - IIa	Apr-2021
---	145060t	SwitchCut Reamer 4.5x6mm	Rule 6 - IIa	Apr-2021
---	145065t	SwitchCut Reamer 4.5x6.5mm	Rule 6 - IIa	Apr-2021
---	145070t	Switchcut Reamer 4.5 x 7.0mm	Rule 6 - IIa	Apr-2021
---	145075t	Switchcut Reamer 4.5 x 7.5mm	Rule 6 - IIa	Apr-2021
---	145080t	SwitchCut Reamer 4.5x8mm	Rule 6 - IIa	Apr-2021
---	145085t	SwitchCut Reamer 4.5x8.5mm	Rule 6 - IIa	Apr-2021
---	145090t	SwitchCut Reamer 4.5x9mm	Rule 6 - IIa	Apr-2021
---	145095t	SwitchCut Reamer 4.5x9.5mm	Rule 6 - IIa	Apr-2021
---	145100t	SwitchCut Reamer 4.5x10mm	Rule 6 - IIa	Apr-2021
---	160110t	SwitchCut Reamer 6x11mm	Rule 6 - IIa	Apr-2021
---	160120t	SwitchCut Reamer 6x12mm	Rule 6 - IIa	Apr-2021
---	146000t	Nitinol Loop Passer	Rule 6 - IIa	Apr-2021

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
234-111-040	114040st	VersiTomic Low Profile Reamer Ø4.0 mm	Rule 6 - IIa	Aug-2023
234-111-045	114045st	VersiTomic Low Profile Reamer Ø4.5 mm	Rule 6 - IIa	Aug-2023
234-111-050	114050st	VersiTomic Low Profile Reamer Ø5.0 mm	Rule 6 - IIa	Aug-2023
234-111-055	114055st	VersiTomic Low Profile Reamer Ø5.5 mm	Rule 6 - IIa	Aug-2023
234-111-060	114060st	VersiTomic Low Profile Reamer Ø6.0 mm	Rule 6 - IIa	Aug-2023
234-111-065	114065st	VersiTomic Low Profile Reamer Ø6.5 mm	Rule 6 - IIa	Aug-2023
234-111-070	114070st	VersiTomic Low Profile Reamer Ø7.0 mm	Rule 6 - IIa	Aug-2023
234-111-075	114075st	VersiTomic Low Profile Reamer Ø7.5 mm	Rule 6 - IIa	Aug-2023
234-111-080	114080st	VersiTomic Low Profile Reamer Ø8.0 mm	Rule 6 - IIa	Aug-2023
234-111-085	114085st	VersiTomic Low Profile Reamer Ø8.5 mm	Rule 6 - IIa	Aug-2023
234-111-090	114090st	VersiTomic Low Profile Reamer Ø9.0 mm	Rule 6 - IIa	Aug-2023
234-111-095	114095st	VersiTomic Low Profile Reamer Ø9.5 mm	Rule 6 - IIa	Aug-2023
234-111-100	114100st	VersiTomic Low Profile Reamer Ø10.0 mm	Rule 6 - IIa	Aug-2023
234-111-105	114105st	VersiTomic Low Profile Reamer Ø10.5 mm	Rule 6 - IIa	Aug-2023
234-111-110	114110st	VersiTomic Low Profile Reamer Ø11.0 mm	Rule 6 - IIa	Aug-2023
234-111-120	114120st	VersiTomic Low Profile Reamer Ø12.0 mm	Rule 6 - IIa	Aug-2023
234-111-130	114130st	VersiTomic Low Profile Reamer Ø13.0 mm	Rule 6 - IIa	Aug-2023

Kategoria: Przeciągacz szwów chirurgicznych SpeedSnare™

Kod GMDN: 57874

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
110030129	253001bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Up	Rule 6 - IIa	Mar-2017
110030130	253002bsm	SpeedSnare™ Surgical Suture Passer 60 Deg Up	Rule 6 - IIa	Mar-2017
110030131	253003bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Right	Rule 6 - IIa	Mar-2017
110030132	253004bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Left	Rule 6 - IIa	Mar-2017
110030133	253005bsm	SpeedSnare™ Surgical Suture Passer Straight	Rule 6 - IIa	Mar-2017
110030140	253006bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Reverse	Rule 6 - IIa	Jul-2019
110030141	253008bsm	SpeedSnare™ Surgical Suture Passer 60 Deg Reverse	Rule 6 - IIa	Jul-2019

Kategoria: Ostrza biodrowe

Kod GMDN: 37445

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
169420bsm	169420bsm	Blunt Curved Blade	Rule 6 - IIa	Sep-2016
169430bsm	169430bsm	Blunt Tip One Side Blade	Rule 6 - IIa	Sep-2016
169431bsm	169431bsm	Curved Hip Blade, Sharp Tip	Rule 6 - IIa	Sep-2016
169420t	169420t	Blunt curved Hip Blade (equivalent to Blunt Curved Blade)	Rule 6 - IIa	May-2023
169430t	169430t	Blunt One Side Hip Blade (equivalent to Blunt Tip One Side Blade)	Rule 6 - IIa	May-2023
169440t	169440t	Curved Hip Blade, Sharp Tip (equivalent to Curved Hip Blade, Sharp Tip)	Rule 6 - IIa	May2023

Kategoria: Zestaw dostępu do biodra

Kod GMDN: 44052

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
640410bsm	640410bsm	Hip Access Kit	Rule 6 - IIa	Mar-2017
640420bsm	640420bsm	Hip Access Kit with Curved Blunt Blade	Rule 6 - IIa	Mar-2017
640430bsm	640430bsm	Hip Access Kit with Straight Blunt One Sided Blade	Rule 6 - IIa	Mar-2017
640431bsm	640431bsm	Hip Access Kit with Curved Sharp Blade	Rule 6 - IIa	Mar-2017

Kategoria: Zestaw instrumentów Hammertoe

Kod GMDN: 44052

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
THN00001	120030oss	Hammertoe Instrument Kit, Size Medium	Rule 6 - IIa	Jun-2018
THN00007	120026oss	Hammertoe Instrument Kit, Size Small	Rule 6 - IIa	Jun-2018
THN00008	120034oss	Hammertoe Instrument Kit, Size Large	Rule 6 - IIa	Jun-2018
THN00055	130240-30oss	Orthopedic Nail Instrument Kit 2.4 x 30 mm	Rule 6 - IIa	March-2020
THN00056	130240-50oss	Orthopedic Nail Instrument Kit 2.4 x 50 mm	Rule 6 - IIa	March-2020
THN00070	130029-30oss	Orthopedic Nail Instrument Kit 2.9 x 30 mm	Rule 6 - IIa	March-2020
THN00071	130029-50oss	Orthopedic Nail Instrument Kit 2.9 x 50 mm	Rule 6 - IIa	March-2020
THN00072	130350-30oss	Orthopedic Nail Instrument Kit 3.5 x 30 mm	Rule 6 - IIa	March-2020
THN00073	130350-50oss	Orthopedic Nail Instrument Kit 3.5 x 50 mm	Rule 6 - IIa	March-2020
THN00074	130400-30oss	Orthopedic Nail Instrument Kit 4.0 x 30 mm	Rule 6 - IIa	March-2020
THN00058	130400-50oss	Orthopedic Nail Instrument Kit 4.0 x 50 mm	Rule 6 - IIa	March-2020

Kategoria: Urządzenie do naprawy łakotki

Kod GMDN: 45612

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
AR-4570	171000ar	FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Dec-2018
AR-4570S	170000ar	FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Dec-2018
AR-4570R	173000ar	FiberStitch™ Implant, Reverse Curve with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Sep-2020
AR-4570-24	174000ar	FiberStitch™ Implant, 24° Curve with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Sep-2020

Kategoria: Silikonowa kaniula

Kod GMDN: 58752

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
3910-080-020	148082st	GATEWAY SILICONE CANNULA, 8.0MM X 20MM	Rule 6 - IIa	Mar-2019
3910-080-030	148083st	GATEWAY SILICONE CANNULA, 8.0MM X 30MM	Rule 6 - IIa	Mar-2019
3910-080-040	148084st	GATEWAY SILICONE CANNULA, 8.0MM X 40MM	Rule 6 - IIa	Mar-2019
3910-080-050	148085st	GATEWAY SILICONE CANNULA, 8.0MM X 50MM	Rule 6 - IIa	Mar-2019
3910-012-030	148123st	GATEWAY SILICONE CANNULA, 12.0MM X 30MM	Rule 6 - IIa	Mar-2019
3910-012-040	148124st	GATEWAY SILICONE CANNULA, 12.0MM X 40MM	Rule 6 - IIa	Mar-2019
---	148082t	SILICONE CANNULA, 8.0mm X 20mm	Rule 6 - IIa	Apr-2021
---	148083t	SILICONE CANNULA, 8.0mm X 30mm	Rule 6 - IIa	Apr-2021
---	148123t	SILICONE CANNULA 12.0mm X 30mm	Rule 6 - IIa	Apr-2021
---	148124t	SILICONE CANNULA 12.0mm X 40mm	Rule 6 - IIa	Apr-2021
---	148084t	SILICONE CANNULA, 8.0mm X 40mm	Rule 6 - IIa	Apr-2021
---	148085t	SILICONE CANNULA, 8.0mm X 50mm	Rule 6 - IIa	Apr-2021
210251	148082m	6mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210252	148083m	8mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210253	148123m	10mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210254	148124m	12mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210242	148130m	10X30mm Flexible Cannula	Rule 6 - IIa	Nov-2023
110048000	148083bsm	El Passo™ Cannula 8mm x 30mm	Rule 6 - IIa	Nov-2023
110048001	148084bsm	El Passo™ Cannula 8mm x 40mm	Rule 6 - IIa	Nov-2023

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
110048002	148085bsm	El Passo™ Cannula 8mm x 50mm	Rule 6 - IIa	Nov-2023
110048004	148150bsm	El Passo™ Cannula 10mm x 50mm	Rule 6 - IIa	Nov-2023
148082cn	148082cn	CONMED 8mm x 20mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148083cn	148083cn	CONMED 8mm x 30mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148085cn	148085cn	CONMED 8mm x 50mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148124cn	148124cn	CONMED 12mm x 40mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148130cn	148130cn	CONMED 10mm x 30mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148150cn	148150cn	CONMED 10mm x 50mm Flexible Cannula	Rule 6 - IIa	Nov-2023

Kategoria: Wiertło

Kod GMDN: 61235

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
AR-1204FF	144000ar	FlipCutter® III Drill	Rule 6 - IIa	Apr-2019
C19790-01	144200ar	FlipCutter® III Drill	Rule 6 - IIa	Feb-2020

Kategoria: Przeciągacz szwów

Kod GMDN: 57874

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
110038984	254001bsm	Dragon Tongue Suture Passer	Rule 6 - IIa	Jul-2019
AR-7070	255001ar	CapsuleStitch™ Suture Passer (equivalent to Dragon Tongue Suture Passer)	Rule 6 - IIa	May-2023

Kategoria: System kotwic VERSALoop™

Kod GMDN: 45062 , 61235

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
210165	514015SSm	VERSALoop™ Anchor 1 Suture, 1.5mm	Rule 8 - IIb	Oct-2020
210166	514015STm	VERSALoop™ Anchor 1 Tape, 1.5mm	Rule 8 - IIb	Oct-2020
210167	514018DSm	VERSALoop™ Anchor 2 Suture, 1.8mm	Rule 8 - IIb	Oct-2020

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
210168	514018DTm	VERSALOOP™ Anchor 2 Tape, 1.8mm	Rule 8 - IIb	Oct-2020
210169	514025DSm	VERSALOOP™ Anchor 2 Suture, 2.5mm	Rule 8 - IIb	Oct-2020
210170	514025DTm	VERSALOOP™ Anchor 2 Tape, 2.5mm	Rule 8 - IIb	Oct-2020
210171	514025Tsm	VERSALOOP™ Anchor 3 Suture, 2.5mm	Rule 8 - IIb	Oct-2020
210215	514376m	VERSALOOP™ Anchor XL 1 Suture, 1.5mm	Rule 8 - IIb	Oct-2020
210216	514377m	VERSALOOP™ Anchor XL 1 Tape, 1.5mm	Rule 8 - IIb	Oct-2020
210199	514001m	VERSALOOP™ 1.5mm Disposable Drill	Rule 6 - IIa	Oct-2020
210203	514002m	VERSALOOP™ 1.8mm Disposable Drill	Rule 6 - IIa	Oct-2020
210221	514381m	VERSALOOP™ XL 1.5mm Disposable Drill	Rule 6 - IIa	Oct-2020
210223	514383m	VERSALOOP™ Self-Punching Anchor 2 Suture, 2.5mm	Rule 8 - IIb	Apr-2021
210224	514384m	VERSALOOP™ Self-Punching Anchor 2 Tape, 2.5mm	Rule 8 - IIb	Apr-2021
210225	514385m	VERSALOOP™ Self-Punching Anchor 3 Suture, 2.5mm	Rule 8 - IIb	Apr-2021

Kategoria: System bezwęzłowych kotwic Betta Link™

Kod GMDN: 45062 , 61235

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
110045154	180100bsm	Betta Link Knotless - Implant Kit	Rule 8 - IIb	Mar-2021
110045160	180200bsm	Betta Link Knotless Long - Implant Kit	Rule 8 - IIb	Mar-2021
110045149	181100bsm	Betta Link Knotless - Implant Only	Rule 8 - IIb	Mar-2021
110045155	181200bsm	Betta Link Knotless Long - Implant Only	Rule 8 - IIb	Mar-2021
110045152	183100bsm	Betta Link Disposable Hard Bone Drill Bit	Rule 6 - IIa	Mar-2021
110045153	183200bsm	Betta Link Disposable Soft Bone Drill Bit	Rule 6 - IIa	Mar-2021
110045158	183300bsm	Betta Link Long Disposable Hard Bone Drill Bit	Rule 6 - IIa	Mar-2021
110045589	183400bsm	Betta Link Short Disposable Drill Bit	Rule 6 - IIa	Mar-2021
110045591	185100bsm	2.4 MM Short Disposable Drill Bit	Rule 6 - IIa	Mar-2021
110045590	185200bsm	3.75 MM Short Disposable Drill Bit	Rule 6 - IIa	Mar-2021

Kategoria: Guziki z nacięciem

Kod GMDN: 65038

Nr modelu	Nr katalog.	Opis produktu	Klasyfikacja	Data wpr. do obrotu
---	141300t	Slotted Button, Concave Round 11mm	Rule 8 - Ilb	Apr-2021
---	141200t	Slotted Button, Concave Round 14mm	Rule 8 - Ilb	Apr-2021
---	141100t	Slotted Button, Concave Round 20mm	Rule 8 - Ilb	Apr-2021
---	141400t	Slotted Button, Flat 8 X 12mm	Rule 8 - Ilb	Apr-2021
---	141500t	Slotted Button, Flat 14mm	Rule 8 - Ilb	Apr-2021
234-100-001	141300st	ProCinch, Slotted Button, Concave Round 11mm	Rule 8 - Ilb	Apr-2021
234-100-002	141200st	ProCinch, Slotted Button, Concave Round 14mm	Rule 8 - Ilb	Apr-2021
234-100-003	141100st	ProCinch, Slotted Button, Concave Round 20mm	Rule 8 - Ilb	Apr-2021
234-100-004	141400st	ProCinch, Slotted Button, Flat 8 X 12mm	Rule 8 - Ilb	Apr-2021
234-100-005	141500st	ProCinch, Slotted Button, Flat 14mm	Rule 8 - Ilb	Apr-2021
210291	141400m	RIGIDLOOP AB 11 mm FLAT	Rule 8 - Ilb	Apr-2021
210292	141300m	RIGIDLOOP AB 11 mm CONCAVE	Rule 8 - Ilb	Apr-2021
210293	141500m	RIGIDLOOP AB 14 mm FLAT	Rule 8 - Ilb	Apr-2021
210294	141200m	RIGIDLOOP AB 14 mm CONCAVE	Rule 8 - Ilb	Apr-2021
210296	141100m	RIGIDLOOP AB 20 mm CONCAVE	Rule 8 - Ilb	Apr-2021
110045856	141100bsm	TOGGLELOC CLIP-ON BUTTON 20MM	Rule 8 - Ilb	Apr-2021
110045855	141200bsm	TOGGLELOC CLIP-ON BUTTON 14MM	Rule 8 - Ilb	Apr-2021
110045854	141300bsm	TOGGLELOC CLIP-ON BUTTON 11MM	Rule 8 - Ilb	Apr-2021
110045857	141400bsm	TOGGLELOC CLIP-ON BUTTON 8X12MM	Rule 8 - Ilb	Apr-2021
110045858	141500bsm	TOGGLELOC CLIP-ON BUTTON 14MM FLAT	Rule 8 - Ilb	Apr-2021



DECLARATION OF CONFORMITY

European Medical Device Directive 93/42/EEC

Manufacturer: **T.A.G. MEDICAL PRODUCTS CORPORATION LTD.**
Kibbutz Gaaton 2513000 Israel
Tel: (972) 4 9858400
Fax: (972) 4 9858404
E-mail: tagltd@netvision.net.il

EC Authorized Representative: **MedNet EC-REP GmbH**
Borkstrasse 10
48163 Munster, Germany
Phone: +49 251 32266-0

I, the undersigned, hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number n°32655-22 and complementary document number n°37072 Rev.8, delivered by GMED, 1, rue Gaston Boissier, 75015 Paris, France, Notified Body Identification Number 0459, in accordance with Annex II of the Council Directives 93/42/EEC of 14 June 1993 concerning medical devices.

This declaration is supported by the Quality System certificate for the products concerned, in accordance with Annex II of the EC-Directive. The conformity to quality assurance set out in the said ISO 13485:2016, Conformity Certificate number; n°32657, issued and delivered by GMED, 1, rue Gaston Boissier, 75015 Paris, France.

Issue place and date: Gaaton, 09-May-2024

Signature:



Name:

Hagay Sitry

Position

CEO

This certificate is valid until 31-Dec-2027

Annex - Product list

This product list belongs to the Declaration of Conformity identified by T.A.G. Medical Products and specifies the CE marked products concerned that T.A.G. Medical Products intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The following list identifies the products by Model No. and type.

Category: Implantable Bone Fixation Devices

GMDN Code: 36174

Model No.	Part No.	Product Description	Classification	Placed on the market
la523st20	la523st20m	Latarjet Cortical Screw Set 20 SS	Rule 8 - IIb	Jul-2011
la523st22	la523st22m	Latarjet Cortical Screw Set 22 SS	Rule 8 - IIb	Jul-2011
la523st24	la523st24m	Latarjet Cortical Screw Set 24 SS	Rule 8 - IIb	Jul-2011
la523st26	la523st26m	Latarjet Cortical Screw Set 26 SS	Rule 8 - IIb	Jul-2011
la523st28	la523st28m	Latarjet Cortical Screw Set 28 SS	Rule 8 - IIb	Jul-2011
la523st30	la523st30m	Latarjet Cortical Screw Set 30 SS	Rule 8 - IIb	Jul-2011
la523st32	la523st32m	Latarjet Cortical Screw Set 32 SS	Rule 8 - IIb	Jul-2011
la523st34	la523st34m	Latarjet Cortical Screw Set 34 SS	Rule 8 - IIb	Jul-2011
la523st36	la523st36m	Latarjet Cortical Screw Set 36 SS	Rule 8 - IIb	Nov-2008
la523st38	la523st38m	Latarjet Cortical Screw Set 38 SS	Rule 8 - IIb	Nov-2008
la523st40	la523st40m	Latarjet Cortical Screw Set 40 SS	Rule 8 - IIb	Nov-2008
la523st42	la523st42m	Latarjet Cortical Screw Set 42 SS	Rule 8 - IIb	Nov-2008
la523st44	la523st44m	Latarjet Cortical Screw Set 44 SS	Rule 8 - IIb	Jun-2009
la523st46	la523st46m	Latarjet Cortical Screw Set 46 SS	Rule 8 - IIb	Jun-2009
la523st48	la523st48m	Latarjet Cortical Screw Set 48 SS	Rule 8 - IIb	Jun-2009
la52320	la52320m	Latarjet Cortical Screw Set 20 Ti	Rule 8 - IIb	Jul-2011
la52322	la52322m	Latarjet Cortical Screw Set 22 Ti	Rule 8 - IIb	Jul-2011
la52324	la52324m	Latarjet Cortical Screw Set 24 Ti	Rule 8 - IIb	Jul-2011
la52326	la52326m	Latarjet Cortical Screw Set 26 Ti	Rule 8 - IIb	Jul-2011
la52328	la52328m	Latarjet Cortical Screw Set 28 Ti	Rule 8 - IIb	Jul-2011
la52330	la52330m	Latarjet Cortical Screw Set 30 Ti	Rule 8 - IIb	Jul-2011
la52332	la52332m	Latarjet Cortical Screw Set 32 Ti	Rule 8 - IIb	Jul-2011
la52334	la52334m	Latarjet Cortical Screw Set 34 Ti	Rule 8 - IIb	Jul-2011
la52336	la52336m	Latarjet Cortical Screw Set 36 Ti	Rule 8 - IIb	Nov-2008
la52338	la52338m	Latarjet Cortical Screw Set 38 Ti	Rule 8 - IIb	Nov-2008
la52340	la52340m	Latarjet Cortical Screw Set 40 Ti	Rule 8 - IIb	Nov-2008
la52342	la52342m	Latarjet Cortical Screw Set 42 Ti	Rule 8 - IIb	Nov-2008

Model No.	Part No.	Product Description	Classification	Placed on the market
la52344	la52344m	Latarjet Cortical Screw Set 44 Ti	Rule 8 - IIb	Jun-2009
la52346	la52346m	Latarjet Cortical Screw Set 46 Ti	Rule 8 - IIb	Jun-2009
la52348	la52348m	Latarjet Cortical Screw Set 48 Ti	Rule 8 - IIb	Jun-2009

Category: Latarjet Disposable Kit

GMDN Code: 44093

Model No.	Part No.	Product Description	Classification	Placed on the market
285180	la523dis-setm	Latarjet Disposable Kit	Rule 6 - IIa	Jul-2010
285200	la523bdis-setm	Bristow Disposable Kit	Rule 6 - IIa	Jul-2010

Category: Suture Shuttle

GMDN Code: 57874

Model No.	Part No.	Product Description	Classification	Placed on the market
251001	251001m	Suture Shuttle 25° Left	Rule 6 - IIa	Jan-2009
251002	251002m	Suture Shuttle 25° Right	Rule 6 - IIa	Jan-2009
251003	251003m	Suture Shuttle 45° Left	Rule 6 - IIa	Jan-2009
251004	251004m	Suture Shuttle 45° Right	Rule 6 - IIa	Jan-2009
251005	251005m	Suture Shuttle 90° Up	Rule 6 - IIa	Jan-2009
251006	251006m	Suture Shuttle Straight Hook	Rule 6 - IIa	Jan-2009
251007	251007m	Suture Shuttle Str. Crescent	Rule 6 - IIa	Jan-2009

Category: ArthroTunneler™

GMDN Code: 44093

Model No.	Part No.	Product Description	Classification	Placed on the market
SMB000101	at555000tr	ArthroTunneler Device	Rule 6 - IIa	Dec-2009

Category: Flexible Reamer System

GMDN Code: 47138, 57789

Model No.	Part No.	Product Description	Classification	Placed on the market
234-108-020	tg108020st	Flexible Guide Pin	Rule 6 - IIa	Dec-2009
234-108-200	tg108200st	VersiTomio® Flexible Guide pin (Flexible Guide Pin)	Rule 6 - IIa	Mar-2013
AR-1400FLX	109120s0ar	Flexible Guide Pin for Arthrex® Flexible Reamer	Rule 6 - IIa	Mar-2017
AR-1400F-70	109070ar	Arthrex® Flexible Reamer with Flexible Guide Pin 7 mm	Rule 6 - IIa	Mar-2017
AR-1400F-75	109075ar	Arthrex® Flexible Reamer with Flexible Guide Pin 7.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-80	109080ar	Arthrex® Flexible Reamer with Flexible Guide Pin 8 mm	Rule 6 - IIa	Mar-2017
AR-1400F-85	109085ar	Arthrex® Flexible Reamer with Flexible Guide Pin 8.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-90	109090ar	Arthrex® Flexible Reamer with Flexible Guide Pin 9 mm	Rule 6 - IIa	Mar-2017
AR-1400F-95	109095ar	Arthrex® Flexible Reamer with Flexible Guide Pin 9.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-100	109100ar	Arthrex® Flexible Reamer with Flexible Guide Pin 10 mm	Rule 6 - IIa	Mar-2017
AR-1400F-105	109105ar	Arthrex® Flexible Reamer with Flexible Guide Pin 10.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-110	109110ar	Arthrex® Flexible Reamer with Flexible Guide Pin 11 mm	Rule 6 - IIa	Mar-2017
AR-1400F-115	109115ar	Arthrex® Flexible Reamer with Flexible Guide Pin 11.5 mm	Rule 6 - IIa	Mar-2017
AR-1400F-120	109120ar	Arthrex® Flexible Reamer with Flexible Guide Pin 12 mm	Rule 6 - IIa	Mar-2017
AR-1401F-70	114070ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 7mm	Rule 6 - IIa	Apr-2018
AR-1401F-75	114075ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 7.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-80	114080ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 8mm	Rule 6 - IIa	Apr-2018
AR-1401F-85	114085ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 8.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-90	114090ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 9mm	Rule 6 - IIa	Apr-2018
AR-1401F-95	114095ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 9.5mm	Rule 6 - IIa	Apr-2018

AR-1401F-100	1140100ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 10mm	Rule 6 - IIa	Apr-2018
AR-1401F-105	1140105ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 10.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-110	1140110ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 11mm	Rule 6 - IIa	Apr-2018
AR-1401F-115	1140115ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 11.5mm	Rule 6 - IIa	Apr-2018
AR-1401F-120	1140120ar	Arthrex® Flexible Reamer with Flexible TightRope® Drill Pin 12mm	Rule 6 - IIa	Apr-2018

Category: Suspension Fixation Devices

GMDN Code: 36174

Model No.	Part No.	Product Description	Classification	Placed on the market
234-100-000	tg100000st	G-Lok® with No Loop	Rule 8 -IIb	Jul-2011
234-101-015	tg101015st	G-Lok® with 15mm Loop	Rule 8 -IIb	Jul-2011
234-101-020	tg101020st	G-Lok® with 20mm Loop	Rule 8 -IIb	Jul-2011
234-101-025	tg101025st	G-Lok® with 25mm Loop	Rule 8 -IIb	Jul-2011
234-101-030	tg101030st	G-Lok® with 30mm Loop	Rule 8 -IIb	Jul-2011
234-101-035	tg101035st	G-Lok® with 35mm Loop	Rule 8 -IIb	Jul-2011
234-101-040	tg101040st	G-Lok® with 40mm Loop	Rule 8 -IIb	Jul-2011
234-101-045	tg101045st	G-Lok® with 45mm Loop	Rule 8 -IIb	Jul-2011
234-101-050	tg101050st	G-Lok® with 50mm Loop	Rule 8 -IIb	Jul-2011
234-100-016	tg100016st	G-Lok® XL	Rule 8 -IIb	Jul-2011

Category: Knotilus™ Anchor System

GMDN Code: 45062

Model No.	Part No.	Product Description	Classification	Placed on the market
3910-500-100	500100st	Knotilus™ Anchor, 3.5mm	Rule 8 -IIb	Mar-2012
3910-500-107	500107st	Knotilus™ Implant Loop, 25 mm	Rule 8 -IIb	Mar-2012

Category: ArthroTunneler™ TunnelPro™ System

GMDN Code: 44093

Model No.	Part No.	Product Description	Classification	Placed on the market
SMB100101	at555010tr	ArthroTunneler™ TunnelPro™ System	Rule 8 -IIb	May-2012

Category: Champion® Slider System

GMDN Code: 57874

Model No.	Part No.	Product Description	Classification	Placed on the market
3910-500-750	500750st	Champion® Slider Handle	Rule 6 - IIa	Apr-2013
3910-500-751	500751st	Slider Needle 45° Right	Rule 6 - IIa	Apr-2013
3910-500-752	500752st	Slider Needle 45° Left	Rule 6 - IIa	Apr-2013
3910-500-753	500753st	Slider Needle 25° Right	Rule 6 - IIa	Apr-2013
3910-500-754	500754st	Slider Needle 25° Left	Rule 6 - IIa	Apr-2013
3910-500-755	500755st	Slider Needle Crescent Large	Rule 6 - IIa	Apr-2013
3910-500-756	500756st	Slider Needle Crescent Medium	Rule 6 - IIa	Apr-2013
3910-500-757	500757st	Slider Needle 30° Straight	Rule 6 - IIa	Apr-2013
3910-500-758	500758st	Slider Needle 60° Straight	Rule 6 - IIa	Apr-2013
3910-500-759	500759st	Slider Needle Crescent Large XL	Rule 6 - IIa	Apr-2013
3910-500-760	500760st	Slider Needle Crescent Medium XL	Rule 6 - IIa	Apr-2013
3910-500-761	500761st	Slider Nitinol Shuttle	Rule 6 - IIa	Apr-2013
11457	500750p	Anika Suture Passer Handle	Rule 2 - IIa	Apr-2021
11458	500751p	Anika Suture Passer 45° Right Needle	Rule 6 - IIa	Apr-2021
11459	500752p	Anika Suture Passer 45° Left Needle	Rule 6 - IIa	Apr-2021
11460	500753p	Anika Suture Passer 25° Right Needle	Rule 6 - IIa	Apr-2021
11461	500754p	Anika Suture Passer 25° Left Needle	Rule 6 - IIa	Apr-2021
11462	500755p	Anika Suture Passer Crescent Large Needle	Rule 6 - IIa	Apr-2021
11463	500756p	Anika Suture Passer Crescent Mid Needle	Rule 6 - IIa	Apr-2021
11464	500757p	Anika Suture Passer Str Hook 30° Needle	Rule 6 - IIa	Apr-2021
11465	500758p	Anika Suture Passer Str Hook 60° Needle	Rule 6 - IIa	Apr-2021
11466	500759p	Anika Suture Passer Crescent Hip Large Needle	Rule 6 - IIa	Apr-2021
11467	500760p	Anika Suture Passer Crescent Hip Mid Needle	Rule 6 - IIa	Apr-2021
S36-5011-T	500750su	Slider Handle	Rule 2 - IIa	Apr-2021

Model No.	Part No.	Product Description	Classification	Placed on the market
S36-5012-T	500751su	Slider 45° Right Needle	Rule 6 - IIa	Apr-2021
S36-5013-T	500752su	Slider 45° Left Needle	Rule 6 - IIa	Apr-2021
S36-5014-T	500753su	Slider 25° Right Needle	Rule 6 - IIa	Apr-2021
S36-5015-T	500754su	Slider 25° Left Needle	Rule 6 - IIa	Apr-2021
S36-5016-T	500755su	Slider Crescent Large Needle	Rule 6 - IIa	Apr-2021
S36-5018-T	500756su	Slider Crescent Mid Needle	Rule 6 - IIa	Apr-2021
S36-5019-T	500757su	Slider Str Hook 30° Needle	Rule 6 - IIa	Apr-2021
S36-5020-T	500758su	Slider Str Hook 60° Needle	Rule 6 - IIa	Apr-2021
S36-5021-T	500759su	Slider Crescent Hip Large Needle	Rule 6 - IIa	Apr-2021
S36-5022-T	500760su	Slider Crescent Hip Mid Needle	Rule 6 - IIa	Apr-2021
S36-5023-T	146100su	Nitinol Loop Passer	Rule 6 - IIa	Apr-2021
110045841	500750bsm	Suture Passer Handle	Rule 2 - IIa	Apr-2021
110045842	500751bsm	Suture Passer Needle 45° RIGHT	Rule 6 - IIa	Apr-2021
110045843	500752bsm	Suture Passer Needle 45° LEFT	Rule 6 - IIa	Apr-2021
110045844	500753bsm	Suture Passer Needle 25° RIGHT	Rule 6 - IIa	Apr-2021
110045845	500754bsm	Suture Passer Needle 25° LEFT	Rule 6 - IIa	Apr-2021
110045846	500755bsm	Suture Passer Needle LRG CRESCENT	Rule 6 - IIa	Apr-2021
110045847	500756bsm	Suture Passer Needle MID CRESCENT	Rule 6 - IIa	Apr-2021
110045848	500757bsm	Suture Passer Needle 30° UP	Rule 6 - IIa	Apr-2021
110045849	500758bsm	Suture Passer Needle 60° UP	Rule 6 - IIa	Apr-2021
110045850	500759bsm	Suture Passer Needle HIP LRG CRESCENT	Rule 6 - IIa	Apr-2021
110045851	500760bsm	Suture Passer Needle HIP MID CRESCENT	Rule 6 - IIa	Apr-2021
---	500750t	Slider Handle	Rule 2 - IIa	Apr-2021
---	500751t	Slider 45° Right Needle	Rule 6 - IIa	Apr-2021
---	500752t	Slider 45° Left Needle	Rule 6 - IIa	Apr-2021
---	500753t	Slider 25° Right Needle	Rule 6 - IIa	Apr-2021
---	500754t	Slider 25° Left Needle	Rule 6 - IIa	Apr-2021
---	500755t	Slider Crescent Large Needle	Rule 6 - IIa	Apr-2021
---	500756t	Slider Crescent Mid Needle	Rule 6 - IIa	Apr-2021
---	500757t	Slider Str Hook 30° Needle	Rule 6 - IIa	Apr-2021
---	500758t	Slider Str Hook 60° Needle	Rule 6 - IIa	Apr-2021
---	500759t	Slider Crescent Hip Large Needle	Rule 6 - IIa	Apr-2021
---	500760t	Slider Crescent Hip Mid Needle	Rule 6 - IIa	Apr-2021

Category: SwitchCut Disposable Instruments

GMDN Code: 61235, 57874

Model No.	Part No.	Product Description	Classification	Placed on the market
110026885	145060bsm	SwitchCut Reamer 4.5 x 6.0mm	Rule 6 - IIa	Jan-2015
110026886	145065bsm	SwitchCut Reamer 4.5 x 6.5mm	Rule 6 - IIa	Jan-2015
110026887	145070bsm	SwitchCut Reamer 4.5 x 7.0mm	Rule 6 - IIa	Jan-2015
110026888	145075bsm	SwitchCut Reamer 4.5 x 7.5mm	Rule 6 - IIa	Jan-2015
110026889	145080bsm	SwitchCut Reamer 4.5 x 8.0mm	Rule 6 - IIa	Jan-2015
110026890	145085bsm	SwitchCut Reamer 4.5 x 8.5mm	Rule 6 - IIa	Jan-2015
110026891	145090bsm	SwitchCut Reamer 4.5 x 9.0mm	Rule 6 - IIa	Jan-2015
110026892	145095bsm	SwitchCut Reamer 4.5 x 9.5mm	Rule 6 - IIa	Jan-2015
110026893	145100bsm	SwitchCut Reamer 4.5 x 10.0mm	Rule 6 - IIa	Jan-2015
110026894	160105bsm	SwitchCut Reamer 6.0 x 10.5mm	Rule 6 - IIa	Jan-2015
110026895	160110bsm	SwitchCut Reamer 6.0 x 11.0mm	Rule 6 - IIa	Jan-2015
110026896	160115bsm	SwitchCut Reamer 6.0 x 11.5mm	Rule 6 - IIa	Jan-2015
110026897	160120bsm	SwitchCut Reamer 6.0 x 12.0mm	Rule 6 - IIa	Jan-2015
110026884	146000bsm	Nitinol Loop Passer	Rule 6 - IIa	Jan-2015
110027674	147060bsm	SwitchCut Reamer 4.5 x 6.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027675	147065bsm	SwitchCut Reamer 4.5 x 6.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027676	147070bsm	SwitchCut Reamer 4.5 x 7.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027677	147075bsm	SwitchCut Reamer 4.5 x 7.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027678	147080bsm	SwitchCut Reamer 4.5 x 8.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027679	147085bsm	SwitchCut Reamer 4.5 x 8.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027680	147090bsm	SwitchCut Reamer 4.5 x 9.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027681	147095bsm	SwitchCut Reamer 4.5 x 9.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027682	147100bsm	SwitchCut Reamer 4.5 x 10.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027683	161105bsm	SwitchCut Reamer 6.0 x 10.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027684	161110bsm	SwitchCut Reamer 6.0 x 11.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
110027685	161115bsm	SwitchCut Reamer 6.0 x 11.5mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015

Model No.	Part No.	Product Description	Classification	Placed on the market
110027686	161120bsm	SwitchCut Reamer 6.0 x 12.0mm w/Nitinol Passers	Rule 6 - IIa	Jan-2015
0234-109-060	145060st	Retrograde Reamer 4.5 x 6.0mm	Rule 6 - IIa	Nov-2019
0234-109-065	145065st	Retrograde Reamer 4.5 x 6.5mm	Rule 6 - IIa	Nov-2019
0234-109-070	145070st	Retrograde Reamer 4.5 x 7.0mm	Rule 6 - IIa	Nov-2019
0234-109-075	145075st	Retrograde Reamer 4.5 x 7.5mm	Rule 6 - IIa	Nov-2019
0234-109-080	145080st	Retrograde Reamer 4.5 x 8.0mm	Rule 6 - IIa	Nov-2019
0234-109-085	145085st	Retrograde Reamer 4.5 x 8.5mm	Rule 6 - IIa	Nov-2019
0234-109-090	145090st	Retrograde Reamer 4.5 x 9.0mm	Rule 6 - IIa	Nov-2019
0234-109-095	145095st	Retrograde Reamer 4.5 x 9.5mm	Rule 6 - IIa	Nov-2019
0234-109-110	145100st	Retrograde Reamer 4.5 x 10.0mm	Rule 6 - IIa	Nov-2019
0234-109-111	145110st	Retrograde Reamer 6.0 x 11.0mm	Rule 6 - IIa	Nov-2019
0234-109-112	145120st	Retrograde Reamer 6.0 x 12.0mm	Rule 6 - IIa	Nov-2019
0234-109-005	146000st	Nitinol Wires	Rule 6 - IIa	Nov-2019
11469	145060p	Anika Retro Reamer 4.5 x 6mm	Rule 6 - IIa	Apr-2021
11470	145065p	Anika Retro Reamer 4.5 x 6.5mm	Rule 6 - IIa	Apr-2021
11471	145070p	Anika Retro Reamer 4.5 x 7mm	Rule 6 - IIa	Apr-2021
11472	145075p	Anika Retro Reamer 4.5 x 7.5mm	Rule 6 - IIa	Apr-2021
11473	145080p	Anika Retro Reamer 4.5 x 8mm	Rule 6 - IIa	Apr-2021
11474	145085p	Anika Retro Reamer 4.5 x 8.5mm	Rule 6 - IIa	Apr-2021
11475	145090p	Anika Retro Reamer 4.5 x 9mm	Rule 6 - IIa	Apr-2021
11476	145095p	Anika Retro Reamer 4.5 x 9.5mm	Rule 6 - IIa	Apr-2021
11477	145100p	Anika Retro Reamer 4.5 x 10mm	Rule 6 - IIa	Apr-2021
11478	160110p	Anika Retro Reamer 6 x 11mm	Rule 6 - IIa	Apr-2021
11479	160120p	Anika Retro Reamer 6 x 12mm	Rule 6 - IIa	Apr-2021
11468	146000p	Anika Suture Passer Shuttle (Nitinol)	Rule 6 - IIa	Apr-2021
---	145060t	SwitchCut Reamer 4.5x6mm	Rule 6 - IIa	Apr-2021
---	145065t	SwitchCut Reamer 4.5x6.5mm	Rule 6 - IIa	Apr-2021
---	145070t	Switchcut Reamer 4.5 x 7.0mm	Rule 6 - IIa	Apr-2021
---	145075t	Switchcut Reamer 4.5 x 7.5mm	Rule 6 - IIa	Apr-2021
---	145080t	SwitchCut Reamer 4.5x8mm	Rule 6 - IIa	Apr-2021
---	145085t	SwitchCut Reamer 4.5x8.5mm	Rule 6 - IIa	Apr-2021
---	145090t	SwitchCut Reamer 4.5x9mm	Rule 6 - IIa	Apr-2021
---	145095t	SwitchCut Reamer 4.5x9.5mm	Rule 6 - IIa	Apr-2021
---	145100t	SwitchCut Reamer 4.5x10mm	Rule 6 - IIa	Apr-2021
---	160110t	SwitchCut Reamer 6x11mm	Rule 6 - IIa	Apr-2021
---	160120t	SwitchCut Reamer 6x12mm	Rule 6 - IIa	Apr-2021
---	146000t	Nitinol Loop Passer	Rule 6 - IIa	Apr-2021

Model No.	Part No.	Product Description	Classification	Placed on the market
234-111-040	114040st	VersiTomic Low Profile Reamer Ø4.0 mm	Rule 6 - IIa	Aug-2023
234-111-045	114045st	VersiTomic Low Profile Reamer Ø4.5 mm	Rule 6 - IIa	Aug-2023
234-111-050	114050st	VersiTomic Low Profile Reamer Ø5.0 mm	Rule 6 - IIa	Aug-2023
234-111-055	114055st	VersiTomic Low Profile Reamer Ø5.5 mm	Rule 6 - IIa	Aug-2023
234-111-060	114060st	VersiTomic Low Profile Reamer Ø6.0 mm	Rule 6 - IIa	Aug-2023
234-111-065	114065st	VersiTomic Low Profile Reamer Ø6.5 mm	Rule 6 - IIa	Aug-2023
234-111-070	114070st	VersiTomic Low Profile Reamer Ø7.0 mm	Rule 6 - IIa	Aug-2023
234-111-075	114075st	VersiTomic Low Profile Reamer Ø7.5 mm	Rule 6 - IIa	Aug-2023
234-111-080	114080st	VersiTomic Low Profile Reamer Ø8.0 mm	Rule 6 - IIa	Aug-2023
234-111-085	114085st	VersiTomic Low Profile Reamer Ø8.5 mm	Rule 6 - IIa	Aug-2023
234-111-090	114090st	VersiTomic Low Profile Reamer Ø9.0 mm	Rule 6 - IIa	Aug-2023
234-111-095	114095st	VersiTomic Low Profile Reamer Ø9.5 mm	Rule 6 - IIa	Aug-2023
234-111-100	114100st	VersiTomic Low Profile Reamer Ø10.0 mm	Rule 6 - IIa	Aug-2023
234-111-105	114105st	VersiTomic Low Profile Reamer Ø10.5 mm	Rule 6 - IIa	Aug-2023
234-111-110	114110st	VersiTomic Low Profile Reamer Ø11.0 mm	Rule 6 - IIa	Aug-2023
234-111-120	114120st	VersiTomic Low Profile Reamer Ø12.0 mm	Rule 6 - IIa	Aug-2023
234-111-130	114130st	VersiTomic Low Profile Reamer Ø13.0 mm	Rule 6 - IIa	Aug-2023

Category: SpeedSnare™ Surgical Suture Passer
GMDN Code: 57874

Model No.	Part No.	Product Description	Classification	Placed on the market
110030129	253001bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Up	Rule 6 - IIa	Mar-2017
110030130	253002bsm	SpeedSnare™ Surgical Suture Passer 60 Deg Up	Rule 6 - IIa	Mar-2017
110030131	253003bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Right	Rule 6 - IIa	Mar-2017
110030132	253004bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Left	Rule 6 - IIa	Mar-2017
110030133	253005bsm	SpeedSnare™ Surgical Suture Passer Straight	Rule 6 - IIa	Mar-2017
110030140	253006bsm	SpeedSnare™ Surgical Suture Passer 30 Deg Reverse	Rule 6 - IIa	Jul-2019
110030141	253008bsm	SpeedSnare™ Surgical Suture Passer 60 Deg Reverse	Rule 6 - IIa	Jul-2019

Category: Hip Blades

GMDN Code: 37445

Model No.	Part No.	Product Description	Classification	Placed on the market
169420bsm	169420bsm	Blunt Curved Blade	Rule 6 - IIa	Sep-2016
169430bsm	169430bsm	Blunt Tip One Side Blade	Rule 6 - IIa	Sep-2016
169431bsm	169431bsm	Curved Hip Blade, Sharp Tip	Rule 6 - IIa	Sep-2016
169420t	169420t	Blunt curved Hip Blade (equivalent to Blunt Curved Blade)	Rule 6 - IIa	May-2023
169430t	169430t	Blunt One Side Hip Blade (equivalent to Blunt Tip One Side Blade)	Rule 6 - IIa	May-2023
169440t	169440t	Curved Hip Blade, Sharp Tip (equivalent to Curved Hip Blade, Sharp Tip)	Rule 6 - IIa	May2023

Category: Hip Access Kit

GMDN Code: 44052

Model No.	Part No.	Product Description	Classification	Placed on the market
640410bsm	640410bsm	Hip Access Kit	Rule 6 - IIa	Mar-2017
640420bsm	640420bsm	Hip Access Kit with Curved Blunt Blade	Rule 6 - IIa	Mar-2017
640430bsm	640430bsm	Hip Access Kit with Straight Blunt One Sided Blade	Rule 6 - IIa	Mar-2017
640431bsm	640431bsm	Hip Access Kit with Curved Sharp Blade	Rule 6 - IIa	Mar-2017

Category: Hammertoe Instrument Kit

GMDN Code: 44052

Model No.	Part No.	Product Description	Classification	Placed on the market
THN00001	120030oss	Hammertoe Instrument Kit, Size Medium	Rule 6 - IIa	Jun-2018
THN00007	120026oss	Hammertoe Instrument Kit, Size Small	Rule 6 - IIa	Jun-2018
THN00008	120034oss	Hammertoe Instrument Kit, Size Large	Rule 6 - IIa	Jun-2018
THN00055	130240-30oss	Orthopedic Nail Instrument Kit 2.4 x 30 mm	Rule 6 - IIa	March-2020
THN00056	130240-50oss	Orthopedic Nail Instrument Kit 2.4 x 50 mm	Rule 6 - IIa	March-2020
THN00070	130029-30oss	Orthopedic Nail Instrument Kit 2.9 x 30 mm	Rule 6 - IIa	March-2020
THN00071	130029-50oss	Orthopedic Nail Instrument Kit 2.9 x 50 mm	Rule 6 - IIa	March-2020
THN00072	130350-30oss	Orthopedic Nail Instrument Kit 3.5 x 30 mm	Rule 6 - IIa	March-2020
THN00073	130350-50oss	Orthopedic Nail Instrument Kit 3.5 x 50 mm	Rule 6 - IIa	March-2020
THN00074	130400-30oss	Orthopedic Nail Instrument Kit 4.0 x 30 mm	Rule 6 - IIa	March-2020
THN00058	130400-50oss	Orthopedic Nail Instrument Kit 4.0 x 50 mm	Rule 6 - IIa	March-2020

Category: Meniscal Repair Device

GMDN Code: 45612

Model No.	Part No.	Product Description	Classification	Placed on the market
AR-4570	171000ar	FiberStitch™ Implant, Curved with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Dec-2018
AR-4570S	170000ar	FiberStitch™ Implant, Straight with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Dec-2018
AR-4570R	173000ar	FiberStitch™ Implant, Reverse Curve with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Sep-2020
AR-4570-24	174000ar	FiberStitch™ Implant, 24° Curve with two Polyester Implants and 2-0 FiberWire® Suture	Rule 8 - IIb	Sep-2020

Category: Silicone Cannula

GMDN Code: 58752

Model No.	Part No.	Product Description	Classification	Placed on the market
3910-080-020	148082st	GATEWAY SILICONE CANNULA, 8.0MM X 20MM	Rule 6 - IIa	Mar-2019
3910-080-030	148083st	GATEWAY SILICONE CANNULA, 8.0MM X 30MM	Rule 6 - IIa	Mar-2019
3910-080-040	148084st	GATEWAY SILICONE CANNULA, 8.0MM X 40MM	Rule 6 - IIa	Mar-2019
3910-080-050	148085st	GATEWAY SILICONE CANNULA, 8.0MM X 50MM	Rule 6 - IIa	Mar-2019
3910-012-030	148123st	GATEWAY SILICONE CANNULA, 12.0MM X 30MM	Rule 6 - IIa	Mar-2019
3910-012-040	148124st	GATEWAY SILICONE CANNULA, 12.0MM X 40MM	Rule 6 - IIa	Mar-2019
---	148082t	SILICONE CANNULA, 8.0mm X 20mm	Rule 6 - IIa	Apr-2021
---	148083t	SILICONE CANNULA, 8.0mm X 30mm	Rule 6 - IIa	Apr-2021
---	148123t	SILICONE CANNULA 12.0mm X 30mm	Rule 6 - IIa	Apr-2021
---	148124t	SILICONE CANNULA 12.0mm X 40mm	Rule 6 - IIa	Apr-2021
---	148084t	SILICONE CANNULA, 8.0mm X 40mm	Rule 6 - IIa	Apr-2021
---	148085t	SILICONE CANNULA, 8.0mm X 50mm	Rule 6 - IIa	Apr-2021
210251	148082m	6mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210252	148083m	8mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210253	148123m	10mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210254	148124m	12mm Flexible Cannula	Rule 6 - IIa	Apr-2021
210242	148130m	10X30mm Flexible Cannula	Rule 6 - IIa	Nov-2023
110048000	148083bsm	El Passo™ Cannula 8mm x 30mm	Rule 6 - IIa	Nov-2023
110048001	148084bsm	El Passo™ Cannula 8mm x 40mm	Rule 6 - IIa	Nov-2023

Model No.	Part No.	Product Description	Classification	Placed on the market
110048002	148085bsm	El Passo™ Cannula 8mm x 50mm	Rule 6 - IIa	Nov-2023
110048004	148150bsm	El Passo™ Cannula 10mm x 50mm	Rule 6 - IIa	Nov-2023
148082cn	148082cn	CONMED 8mm x 20mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148083cn	148083cn	CONMED 8mm x 30mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148085cn	148085cn	CONMED 8mm x 50mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148124cn	148124cn	CONMED 12mm x 40mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148130cn	148130cn	CONMED 10mm x 30mm Flexible Cannula	Rule 6 - IIa	Nov-2023
148150cn	148150cn	CONMED 10mm x 50mm Flexible Cannula	Rule 6 - IIa	Nov-2023

Category: Drill
GMDN Code: 61235

Model No.	Part No.	Product Description	Classification	Placed on the market
AR-1204FF	144000ar	FlipCutter® III Drill	Rule 6 - IIa	Apr-2019
C19790-01	144200ar	FlipCutter® III Drill	Rule 6 - IIa	Feb-2020

Category: Suture Passer
GMDN Code: 57874

Model No.	Part No.	Product Description	Classification	Placed on the market
110038984	254001bsm	Dragon Tongue Suture Passer	Rule 6 - IIa	Jul-2019
AR-7070	255001ar	CapsuleStitch™ Suture Passer (equivalent to Dragon Tongue Suture Passer)	Rule 6 - IIa	May-2023

Category: VERSALOOP™ Anchor System
GMDN Code: 45062 , 61235

Model No.	Part No.	Product Description	Classification	Placed on the market
210165	514015SSm	VERSALOOP™ Anchor 1 Suture, 1.5mm	Rule 8 - IIb	Oct-2020
210166	514015STm	VERSALOOP™ Anchor 1 Tape, 1.5mm	Rule 8 - IIb	Oct-2020
210167	514018DSm	VERSALOOP™ Anchor 2 Suture, 1.8mm	Rule 8 - IIb	Oct-2020

Model No.	Part No.	Product Description	Classification	Placed on the market
210168	514018DTm	VERSALOOP™ Anchor 2 Tape, 1.8mm	Rule 8 - IIb	Oct-2020
210169	514025DSm	VERSALOOP™ Anchor 2 Suture, 2.5mm	Rule 8 - IIb	Oct-2020
210170	514025DTm	VERSALOOP™ Anchor 2 Tape, 2.5mm	Rule 8 - IIb	Oct-2020
210171	514025TSM	VERSALOOP™ Anchor 3 Suture, 2.5mm	Rule 8 - IIb	Oct-2020
210215	514376m	VERSALOOP™ Anchor XL 1 Suture, 1.5mm	Rule 8 - IIb	Oct-2020
210216	514377m	VERSALOOP™ Anchor XL 1 Tape, 1.5mm	Rule 8 - IIb	Oct-2020
210199	514001m	VERSALOOP™ 1.5mm Disposable Drill	Rule 6 - IIa	Oct-2020
210203	514002m	VERSALOOP™ 1.8mm Disposable Drill	Rule 6 - IIa	Oct-2020
210221	514381m	VERSALOOP™ XL 1.5mm Disposable Drill	Rule 6 - IIa	Oct-2020
210223	514383m	VERSALOOP™ Self-Punching Anchor 2 Suture, 2.5mm	Rule 8 - IIb	Apr-2021
210224	514384m	VERSALOOP™ Self-Punching Anchor 2 Tape, 2.5mm	Rule 8 - IIb	Apr-2021
210225	514385m	VERSALOOP™ Self-Punching Anchor 3 Suture, 2.5mm	Rule 8 - IIb	Apr-2021

Category: Betta Link™ Knotless Anchor System

GMDN Code: 45062 , 61235

Model No.	Part No.	Product Description	Classification	Placed on the market
110045154	180100bsm	Betta Link Knotless - Implant Kit	Rule 8 - IIb	Mar-2021
110045160	180200bsm	Betta Link Knotless Long - Implant Kit	Rule 8 - IIb	Mar-2021
110045149	181100bsm	Betta Link Knotless - Implant Only	Rule 8 - IIb	Mar-2021
110045155	181200bsm	Betta Link Knotless Long - Implant Only	Rule 8 - IIb	Mar-2021
110045152	183100bsm	Betta Link Disposable Hard Bone Drill Bit	Rule 6 - IIa	Mar-2021
110045153	183200bsm	Betta Link Disposable Soft Bone Drill Bit	Rule 6 - IIa	Mar-2021
110045158	183300bsm	Betta Link Long Disposable Hard Bone Drill Bit	Rule 6 - IIa	Mar-2021
110045589	183400bsm	Betta Link Short Disposable Drill Bit	Rule 6 - IIa	Mar-2021
110045591	185100bsm	2.4 MM Short Disposable Drill Bit	Rule 6 - IIa	Mar-2021
110045590	185200bsm	3.75 MM Short Disposable Drill Bit	Rule 6 - IIa	Mar-2021

Category: Slotted Buttons

GMDN Code: 65038

Model No.	Part No.	Product Description	Classification	Placed on the market
---	141300t	Slotted Button, Concave Round 11mm	Rule 8 - IIb	Apr-2021
---	141200t	Slotted Button, Concave Round 14mm	Rule 8 - IIb	Apr-2021
---	141100t	Slotted Button, Concave Round 20mm	Rule 8 - IIb	Apr-2021
---	141400t	Slotted Button, Flat 8 X 12mm	Rule 8 - IIb	Apr-2021
---	141500t	Slotted Button, Flat 14mm	Rule 8 - IIb	Apr-2021
234-100-001	141300st	ProCinch, Slotted Button, Concave Round 11mm	Rule 8 - IIb	Apr-2021
234-100-002	141200st	ProCinch, Slotted Button, Concave Round 14mm	Rule 8 - IIb	Apr-2021
234-100-003	141100st	ProCinch, Slotted Button, Concave Round 20mm	Rule 8 - IIb	Apr-2021
234-100-004	141400st	ProCinch, Slotted Button, Flat 8 X 12mm	Rule 8 - IIb	Apr-2021
234-100-005	141500st	ProCinch, Slotted Button, Flat 14mm	Rule 8 - IIb	Apr-2021
210291	141400m	RIGIDLOOP AB 11 mm FLAT	Rule 8 - IIb	Apr-2021
210292	141300m	RIGIDLOOP AB 11 mm CONCAVE	Rule 8 - IIb	Apr-2021
210293	141500m	RIGIDLOOP AB 14 mm FLAT	Rule 8 - IIb	Apr-2021
210294	141200m	RIGIDLOOP AB 14 mm CONCAVE	Rule 8 - IIb	Apr-2021
210296	141100m	RIGIDLOOP AB 20 mm CONCAVE	Rule 8 - IIb	Apr-2021
110045856	141100bsm	TOGGLELOC CLIP-ON BUTTON 20MM	Rule 8 - IIb	Apr-2021
110045855	141200bsm	TOGGLELOC CLIP-ON BUTTON 14MM	Rule 8 - IIb	Apr-2021
110045854	141300bsm	TOGGLELOC CLIP-ON BUTTON 11MM	Rule 8 - IIb	Apr-2021
110045857	141400bsm	TOGGLELOC CLIP-ON BUTTON 8X12MM	Rule 8 - IIb	Apr-2021
110045858	141500bsm	TOGGLELOC CLIP-ON BUTTON 14MM FLAT	Rule 8 - IIb	Apr-2021