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Numero gratuito 900993963



Reg. Imp. PD n. 00401550280 - Cap. Soc. 468.000 i.v.
R.E.A. n. 123527 - Cod.Fisc. e Part. IVA 00401550280

Manufacturer: Sweden & Martina S.p.A.

Address: Via Veneto 10, 35020 – Due Carrare, Padova, Italy

Medical Device: Fixtures

Identification of the product:

CODE	DESCRIPTION 1	DESCRIPTION 2	DIAMETER	HEIGHT	SINGLE USE	CLASS OF RISK 93/42/EEC
E2-ZT-330-085	OUTLINK2 IMPLANT ZIRTI	D.3.30 H.8.5 MM	3.30	8.50	yes	IIB
E2-ZT-330-100	OUTLINK2 IMPLANT ZIRTI	D.3.30 H.10 MM	3.30	10.00	yes	IIB
E2-ZT-330-115	OUTLINK2 IMPLANT ZIRTI	D.3.30 H.11.5 MM	3.30	11.50	yes	IIB
E2-ZT-330-130	OUTLINK2 IMPLANT ZIRTI	D.3.30 H.13 MM	3.30	13.00	yes	IIB
E2-ZT-330-150	OUTLINK2 IMPLANT ZIRTI	D.3.30 H.15 MM	3.30	15.00	yes	IIB
E2-ZT-375-085	OUTLINK2 IMPLANT ZIRTI	D.3.75 H.8.5 MM	3.75	8.50	yes	IIB
E2-ZT-375-100	OUTLINK2 IMPLANT ZIRTI	D.3.75 H.10 MM	3.75	10.00	yes	IIB
E2-ZT-375-115	OUTLINK2 IMPLANT ZIRTI	D.3.75 H.11.5 MM	3.75	11.50	yes	IIB
E2-ZT-375-130	OUTLINK2 IMPLANT ZIRTI	D.3.75 H.13 MM	3.75	13.00	yes	IIB
E2-ZT-375-150	OUTLINK2 IMPLANT ZIRTI	D.3.75 H.15 MM	3.75	15.00	yes	IIB
E2-ZT-410-085	OUTLINK2 IMPLANT ZIRTI	D.4.10 H.8.5 MM	4.10	8.50	yes	IIB
E2-ZT-410-100	OUTLINK2 IMPLANT ZIRTI	D.4.10 H.10 MM	4.10	10.00	yes	IIB
E2-ZT-410-115	OUTLINK2 IMPLANT ZIRTI	D.4.10 H.11.5 MM	4.10	11.50	yes	IIB
E2-ZT-410-130	OUTLINK2 IMPLANT ZIRTI	D.4.10 H.13 MM	4.10	13.00	yes	IIB
E2-ZT-410-150	OUTLINK2 IMPLANT ZIRTI	D.4.10 H.15 MM	4.10	15.00	yes	IIB
E2-ZT-410-180	OUTLINK2 IMPLANT ZIRTI	D.4.10 H.18 MM	4.10	18.00	yes	IIB
E2-ZT-410SP-050	OUTLINK2 SP IMPLANT ZIRTI	D.4.10 H.5 MM	4.10	5.00	yes	IIB
E2-ZT-410SP-070	OUTLINK2 SP IMPLANT ZIRTI	D.4.10 H.7 MM	4.10	7.00	yes	IIB
E2-ZT-410SP-085	OUTLINK2 SP IMPLANT ZIRTI	D.4.10 H.8.5 MM	4.10	8.50	yes	IIB
E2-ZT-410SP-100	OUTLINK2 SP IMPLANT ZIRTI	D.4.10 H.10 MM	4.10	10.00	yes	IIB
E2-ZT-410SP-115	OUTLINK2 SP IMPLANT ZIRTI	D.4.10 H.11.5 MM	4.10	11.50	yes	IIB
E2-ZT-410SP-130	OUTLINK2 SP IMPLANT ZIRTI	D.4.10 H.13 MM	4.10	13.00	yes	IIB
E2-ZT-410SP-150	OUTLINK2 SP IMPLANT ZIRTI	D.4.10 H.15 MM	4.10	15.00	yes	IIB
E2-ZT-500-050	OUTLINK2 IMPLANT ZIRTI	D.5.00 H.5 MM	5.00	5.00	yes	IIB
E2-ZT-500-070	OUTLINK2 IMPLANT ZIRTI	D.5.00 H.7 MM	5.00	7.00	yes	IIB
E2-ZT-500-085	OUTLINK2 IMPLANT ZIRTI	D.5.00 H.8.5 MM	5.00	8.50	yes	IIB



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CODE	DESCRIPTION 1	DESCRIPTION 2	DIAMETER	HEIGHT	SINGLE USE	CLASS OF RISK 93/42/EEC
E2-ZT-500-100	OUTLINK2 IMPLANT ZIRTI	D.5.00 H.10 MM	5.00	10.00	yes	IIB
E2-ZT-500-115	OUTLINK2 IMPLANT ZIRTI	D.5.00 H.11.5 MM	5.00	11.50	yes	IIB
E2-ZT-500-130	OUTLINK2 IMPLANT ZIRTI	D.5.00 H.13 MM	5.00	13.00	yes	IIB
E-VT-330	SURGICAL COVER SCREW OUTLINK2	D.3.30 MM - D.4.10SP	-	-	yes	IIB
E-VT-410	SURGICAL COVER SCREW OUTLINK2	D.3.75 / 4.10 MM	-	-	yes	IIB
E-VT-500	SURGICAL COVER SCREW OUTLINK2	D.5.00 MM	-	-	yes	IIB

Declaration of conformity of the Manufacturer:

Sweden & Martina declares under its sole responsibility that the products mentioned above comply with the requirements of Directive 93/42/EEC, implemented with LD. 46 dated 24/02/1997 and subsequent amendments, as amended by Law 37/2010 of 25 January 2010 implementing Directive 2007/47/EC and the devices are in possession of CE certification issued by the Notified Body CERMET 0476

Elisabetta Martina
Quality Assurance Manager
Sweden & Martina S.p.A.

Due Carrare May 19, 2016



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