

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
U-VT-380-VE	SURGICAL COVER SCREW GLOBAL	D.3.80 MM ,GREEN	-	-	yes	IIB
U-VT-430-BL	SURGICAL COVER SCREW GLOBAL	D.4.30 MM, BLUE	-	-	yes	IIB
U-VT-480-VI	SURGICAL COVER SCREW GLOBAL	D.4.80 MM, MAGENTA	-	-	yes	IIB
U-VT-550-AZ	SURGICAL COVER SCREW GLOBAL	D.5.50 MM, LIGHT BLUE	-	-	yes	IIB
U-ZT-380-085	GLOBAL IMPLANT ZIRTI	D.3.80 H.8.5 MM	3.80	8.50	yes	IIB
U-ZT-380-100	GLOBAL IMPLANT ZIRTI	D.3.80 H.10 MM	3.80	10.00	yes	IIB
U-ZT-380-115	GLOBAL IMPLANT ZIRTI	D.3.80 H.11.5 MM	3.80	11.50	yes	IIB
U-ZT-380-130	GLOBAL IMPLANT ZIRTI	D.3.80 H.13 MM	3.80	13.00	yes	IIB
U-ZT-380-150	GLOBAL IMPLANT ZIRTI	D.3.80 H.15 MM	3.80	15.00	yes	IIB
U-ZT-430-085	GLOBAL IMPLANT ZIRTI	D.4.30 H.8.5 MM	4.30	8.50	yes	IIB
U-ZT-430-100	GLOBAL IMPLANT ZIRTI	D.4.30 H.10 MM	4.30	10.00	yes	IIB
U-ZT-430-115	GLOBAL IMPLANT ZIRTI	D.4.30 H.11.5 MM	4.30	11.50	yes	IIB
U-ZT-430-130	GLOBAL IMPLANT ZIRTI	D.4.30 H.13 MM	4.30	13.00	yes	IIB
U-ZT-430-150	GLOBAL IMPLANT ZIRTI	D.4.30 H.15 MM	4.30	15.00	yes	IIB
U-ZT-480-085	GLOBAL IMPLANT ZIRTI	D.4.80 H.8.5 MM	4.80	8.50	yes	IIB
U-ZT-480-100	GLOBAL IMPLANT ZIRTI	D.4.80 H.10 MM	4.80	10.00	yes	IIB
U-ZT-480-115	GLOBAL IMPLANT ZIRTI	D.4.80 H.11.5 MM	4.80	11.50	yes	IIB
U-ZT-480-130	GLOBAL IMPLANT ZIRTI	D.4.80 H.13 MM	4.80	13.00	yes	IIB
U-ZT-480-150	GLOBAL IMPLANT ZIRTI	D.4.80 H.15 MM	4.80	15.00	yes	IIB
U-ZT-550-085	GLOBAL IMPLANT ZIRTI	D.5.50 H.8.5 MM	5.50	8.50	yes	IIB
U-ZT-550-100	GLOBAL IMPLANT ZIRTI	D.5.50 H.10 MM	5.50	10.00	yes	IIB
U-ZT-550-115	GLOBAL IMPLANT ZIRTI	D.5.50 H.11.5 MM	5.50	11.50	yes	IIB
U-ZT-550-130	GLOBAL IMPLANT ZIRTI	D.5.50 H.13 MM	5.50	13.00	yes	IIB
U-ZT-550-150	GLOBAL IMPLANT ZIRTI	D.5.50 H.15 MM	5.50	15.00	yes	IIB
U-HR-380-085	HR GLOBAL IMPLANT	D.3.80 H.8.5 MM	3.80	8.50	yes	IIB
U-HR-380-100	HR GLOBAL IMPLANT	D.3.80 H.10 MM	3.80	10.00	yes	IIB
U-HR-380-115	HR GLOBAL IMPLANT	D.3.80 H.11.5 MM	3.80	11.50	yes	IIB
U-HR-380-130	HR GLOBAL IMPLANT	D.3.80 H.13 MM	3.80	13.00	yes	IIB
U-HR-380-150	HR GLOBAL IMPLANT	D.3.80 H.15 MM	3.80	15.00	yes	IIB
U-HR-430-085	HR GLOBAL IMPLANT	D.4.30 H.8.5 MM	4.30	8.50	yes	IIB
U-HR-430-100	HR GLOBAL IMPLANT	D.4.30 H.10 MM	4.30	10.00	yes	IIB
U-HR-430-115	HR GLOBAL IMPLANT	D.4.30 H.11.5 MM	4.30	11.50	yes	IIB



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U-HR-430-130	HR GLOBAL IMPLANT	D.4.30 H.13 MM	4.30	13.00	yes	IIB
U-HR-430-150	HR GLOBAL IMPLANT	D.4.30 H.15 MM	4.30	15.00	yes	IIB
U-HR-480-085	HR GLOBAL IMPLANT	D.4.80 H.8.5 MM	4.80	8.50	yes	IIB
U-HR-480-100	HR GLOBAL IMPLANT	D.4.80 H.10 MM	4.80	10.00	yes	IIB
U-HR-480-115	HR GLOBAL IMPLANT	D.4.80 H.11.5 MM	4.80	11.50	yes	IIB
U-HR-480-130	HR GLOBAL IMPLANT	D.4.80 H.13 MM	4.80	13.00	yes	IIB
U-HR-480-150	HR GLOBAL IMPLANT	D.4.80 H.15 MM	4.80	15.00	yes	IIB
U-HR-550-085	HR GLOBAL IMPLANT	D.5.50 H.8.5 MM	5.50	8.50	yes	IIB
U-HR-550-100	HR GLOBAL IMPLANT	D.5.50 H.10 MM	5.50	10.00	yes	IIB
U-HR-550-115	HR GLOBAL IMPLANT	D.5.50 H.11.5 MM	5.50	11.50	yes	IIB
U-HR-550-130	HR GLOBAL IMPLANT	D.5.50 H.13 MM	5.50	13.00	yes	IIB
U-HR-550-150	HR GLOBAL IMPLANT	D.5.50 H.15 MM	5.50	15.00	yes	IIB
U-IB-380-085	GLOBAL IMPLANT HYBRID	D.3.80 H.8.5 MM	3.80	8.50	yes	IIB
U-IB-380-100	GLOBAL IMPLANT HYBRID	D.3.80 H.10 MM	3.80	10.00	yes	IIB
U-IB-380-115	GLOBAL IMPLANT HYBRID	D.3.80 H.11.5 MM	3.80	11.50	yes	IIB
U-IB-380-130	GLOBAL IMPLANT HYBRID	D.3.80 H.13 MM	3.80	13.00	yes	IIB
U-IB-380-150	GLOBAL IMPLANT HYBRID	D.3.80 H.15 MM	3.80	15.00	yes	IIB
U-IB-430-085	GLOBAL IMPLANT HYBRID	D.4.30 H.8.5 MM	4.30	8.50	yes	IIB
U-IB-430-100	GLOBAL IMPLANT HYBRID	D.4.30 H.10 MM	4.30	10.00	yes	IIB
U-IB-430-115	GLOBAL IMPLANT HYBRID	D.4.30 H.11.5 MM	4.30	11.50	yes	IIB
U-IB-430-130	GLOBAL IMPLANT HYBRID	D.4.30 H.13 MM	4.30	13.00	yes	IIB
U-IB-430-150	GLOBAL IMPLANT HYBRID	D.4.30 H.15 MM	4.30	15.00	yes	IIB
U-IB-480-085	GLOBAL IMPLANT HYBRID	D.4.80 H.8.5 MM	4.80	8.50	yes	IIB
U-IB-480-100	GLOBAL IMPLANT HYBRID	D.4.80 H.10 MM	4.80	10.00	yes	IIB
U-IB-480-115	GLOBAL IMPLANT HYBRID	D.4.80 H.11.5 MM	4.80	11.50	yes	IIB
U-IB-480-130	GLOBAL IMPLANT HYBRID	D.4.80 H.13 MM	4.80	13.00	yes	IIB
U-IB-480-150	GLOBAL IMPLANT HYBRID	D.4.80 H.15 MM	4.80	15.00	yes	IIB
U-IB-550-085	GLOBAL IMPLANT HYBRID	D.5.50 H.8.5 MM	5.50	8.50	yes	IIB
U-IB-550-100	GLOBAL IMPLANT HYBRID	D.5.50 H.10 MM	5.50	10.00	yes	IIB
U-IB-550-115	GLOBAL IMPLANT HYBRID	D.5.50 H.11.5 MM	5.50	11.50	yes	IIB
U-IB-550-130	GLOBAL IMPLANT HYBRID	D.5.50 H.13 MM	5.50	13.00	yes	IIB
U-IB-550-150	GLOBAL IMPLANT HYBRID	D.5.50 H.15 MM	5.50	15.00	yes	IIB
U-M-380-085	GLOBAL IMPLANT MACHINED	D.3.80 H.8.5 MM	3.80	8.50	yes	IIB
U-M-380-100	GLOBAL IMPLANT MACHINED	D.3.80 H.10 MM	3.80	10.00	yes	IIB
U-M-380-115	GLOBAL IMPLANT MACHINED	D.3.80 H.11.5 MM	3.80	11.50	yes	IIB
U-M-380-130	GLOBAL IMPLANT MACHINED	D.3.80 H.13 MM	3.80	13.00	yes	IIB
U-M-380-150	GLOBAL IMPLANT MACHINED	D.3.80 H.15 MM	3.80	15.00	yes	IIB
U-M-430-085	GLOBAL IMPLANT MACHINED	D.4.30 H.8.5 MM	4.30	8.50	yes	IIB
U-M-430-100	GLOBAL IMPLANT MACHINED	D.4.30 H.10 MM	4.30	10.00	yes	IIB
U-M-430-115	GLOBAL IMPLANT MACHINED	D.4.30 H.11.5 MM	4.30	11.50	yes	IIB



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U-M-430-130	GLOBAL IMPLANT MACHINED	D.4.30 H.13 MM	4.30	13.00	yes	IIB
U-M-430-150	GLOBAL IMPLANT MACHINED	D.4.30 H.15 MM	4.30	15.00	yes	IIB
U-M-480-085	GLOBAL IMPLANT MACHINED	D.4.80 H.8.5 MM	4.80	8.50	yes	IIB
U-M-480-100	GLOBAL IMPLANT MACHINED	D.4.80 H.10 MM	4.80	10.00	yes	IIB
U-M-480-115	GLOBAL IMPLANT MACHINED	D.4.80 H.11.5 MM	4.80	11.50	yes	IIB
U-M-480-130	GLOBAL IMPLANT MACHINED	D.4.80 H.13 MM	4.80	13.00	yes	IIB
U-M-480-150	GLOBAL IMPLANT MACHINED	D.4.80 H.15 MM	4.80	15.00	yes	IIB
U-M-550-085	GLOBAL IMPLANT MACHINED	D.5.50 H.8.5 MM	5.50	8.50	yes	IIB
U-M-550-100	GLOBAL IMPLANT MACHINED	D.5.50 H.10 MM	5.50	10.00	yes	IIB
U-M-550-115	GLOBAL IMPLANT MACHINED	D.5.50 H.11.5 MM	5.50	11.50	yes	IIB
U-M-550-130	GLOBAL IMPLANT MACHINED	D.5.50 H.13 MM	5.50	13.00	yes	IIB
U-M-550-150	GLOBAL IMPLANT MACHINED	D.5.50 H.15 MM	5.50	15.00	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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