

**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
L-VT-340	SURGICAL COVER SCREW	PRAMA IMPLANT	-	-	yes	IIB
LA-ZT-330-085	PRAMA IMPLANT ZIRTI	D. 3.30 H. 8.5 MM	3.30	8.50	yes	IIB
LA-ZT-330-100	PRAMA IMPLANT ZIRTI	D. 3.30 H. 10 MM	3.30	10.00	yes	IIB
LA-ZT-330-115	PRAMA IMPLANT ZIRTI	D. 3.30 H. 11.5 MM	3.30	11.50	yes	IIB
LA-ZT-330-130	PRAMA IMPLANT ZIRTI	D. 3.30 H. 13 MM	3.30	13.00	yes	IIB
LA-ZT-330-150	PRAMA IMPLANT ZIRTI	D. 3.30 H. 15 MM	3.30	15.00	yes	IIB
LA-ZT-380-085	PRAMA IMPLANT ZIRTI	D. 3.80 H. 8.5 MM	3.80	8.50	yes	IIB
LA-ZT-380-100	PRAMA IMPLANT ZIRTI	D. 3.80 H. 10 MM	3.80	10.00	yes	IIB
LA-ZT-380-115	PRAMA IMPLANT ZIRTI	D. 3.80 H. 11.5 MM	3.80	11.50	yes	IIB
LA-ZT-380-130	PRAMA IMPLANT ZIRTI	D. 3.80 H. 13 MM	3.80	13.00	yes	IIB
LA-ZT-380-150	PRAMA IMPLANT ZIRTI	D. 3.80 H. 15 MM	3.80	15.00	yes	IIB
LA-ZT-425-085	PRAMA IMPLANT ZIRTI	D. 4.25 H. 8.5 MM	4.25	8.50	yes	IIB
LA-ZT-425-100	PRAMA IMPLANT ZIRTI	D. 4.25 H. 10 MM	4.25	10.00	yes	IIB
LA-ZT-425-115	PRAMA IMPLANT ZIRTI	D. 4.25 H. 11.5 MM	4.25	11.50	yes	IIB
LA-ZT-425-130	PRAMA IMPLANT ZIRTI	D. 4.25 H. 13 MM	4.25	13.00	yes	IIB
LA-ZT-425-150	PRAMA IMPLANT ZIRTI	D. 4.25 H. 15 MM	4.25	15.00	yes	IIB
LA-ZT-500-085	PRAMA IMPLANT ZIRTI	D. 5.00 H. 8.5 MM	5.00	8.50	yes	IIB
LA-ZT-500-100	PRAMA IMPLANT ZIRTI	D. 5.00 H. 10 MM	5.00	10.00	yes	IIB
LA-ZT-500-115	PRAMA IMPLANT ZIRTI	D. 5.00 H. 11.5 MM	5.00	11.50	yes	IIB
LA-ZT-500-130	PRAMA IMPLANT ZIRTI	D. 5.00 H. 13 MM	5.00	13.00	yes	IIB
LA-ZT-500-150	PRAMA IMPLANT ZIRTI	D. 5.00 H. 15 MM	5.00	15.00	yes	IIB
LA-M-330-085	PRAMA IMPLANT MACHINED	D. 3.30 H. 8.5 MM	3.30	8.50	yes	IIB
LA-M-330-100	PRAMA IMPLANT MACHINED	D. 3.30 H. 10 MM	3.30	10.00	yes	IIB
LA-M-330-115	PRAMA IMPLANT MACHINED	D. 3.30 H. 11.5 MM	3.30	11.50	yes	IIB
LA-M-330-130	PRAMA IMPLANT MACHINED	D. 3.30 H. 13 MM	3.30	13.00	yes	IIB
LA-M-330-150	PRAMA IMPLANT MACHINED	D. 3.30 H. 15 MM	3.30	15.00	yes	IIB
LA-M-380-085	PRAMA IMPLANT MACHINED	D. 3.80 H. 8.5 MM	3.80	8.50	yes	IIB
LA-M-380-100	PRAMA IMPLANT MACHINED	D. 3.80 H. 10 MM	3.80	10.00	yes	IIB
LA-M-380-115	PRAMA IMPLANT MACHINED	D. 3.80 H. 11.5 MM	3.80	11.50	yes	IIB



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LA-M-380-130	PRAMA IMPLANT MACHINED	D. 3.80 H. 13 MM	3.80	13.00	yes	IIB
LA-M-380-150	PRAMA IMPLANT MACHINED	D. 3.80 H. 15 MM	3.80	15.00	yes	IIB
LA-M-425-085	PRAMA IMPLANT MACHINED	D. 4.25 H. 8.5 MM	4.25	8.50	yes	IIB
LA-M-425-100	PRAMA IMPLANT MACHINED	D. 4.25 H. 10 MM	4.25	10.00	yes	IIB
LA-M-425-115	PRAMA IMPLANT MACHINED	D. 4.25 H. 11.5 MM	4.25	11.50	yes	IIB
LA-M-425-130	PRAMA IMPLANT MACHINED	D. 4.25 H. 13 MM	4.25	13.00	yes	IIB
LA-M-425-150	PRAMA IMPLANT MACHINED	D. 4.25 H. 15 MM	4.25	15.00	yes	IIB
LA-M-500-085	PRAMA IMPLANT MACHINED	D. 5.00 H. 8.5 MM	5.00	8.50	yes	IIB
LA-M-500-100	PRAMA IMPLANT MACHINED	D. 5.00 H. 10 MM	5.00	10.00	yes	IIB
LA-M-500-115	PRAMA IMPLANT MACHINED	D. 5.00 H. 11.5 MM	5.00	11.50	yes	IIB
LA-M-500-130	PRAMA IMPLANT MACHINED	D. 5.00 H. 13 MM	5.00	13.00	yes	IIB
LA-M-500-150	PRAMA IMPLANT MACHINED	D. 5.00 H. 15 MM	5.00	15.00	yes	IIB
LA-IB-330-085	PRAMA IMPLANT HYBRID	D. 3.30 H. 8.5 MM	3.30	8.50	yes	IIB
LA-IB-330-100	PRAMA IMPLANT HYBRID	D. 3.30 H. 10 MM	3.30	10.00	yes	IIB
LA-IB-330-115	PRAMA IMPLANT HYBRID	D. 3.30 H. 11.5 MM	3.30	11.50	yes	IIB
LA-IB-330-130	PRAMA IMPLANT HYBRID	D. 3.30 H. 13 MM	3.30	13.00	yes	IIB
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LA-IB-380-085	PRAMA IMPLANT HYBRID	D. 3.80 H. 8.5 MM	3.80	8.50	yes	IIB
LA-IB-380-100	PRAMA IMPLANT HYBRID	D. 3.80 H. 10 MM	3.80	10.00	yes	IIB
LA-IB-380-115	PRAMA IMPLANT HYBRID	D. 3.80 H. 11.5 MM	3.80	11.50	yes	IIB
LA-IB-380-130	PRAMA IMPLANT HYBRID	D. 3.80 H. 13 MM	3.80	13.00	yes	IIB
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LA-IB-425-100	PRAMA IMPLANT HYBRID	D. 4.25 H. 10 MM	4.25	10.00	yes	IIB
LA-IB-425-115	PRAMA IMPLANT HYBRID	D. 4.25 H. 11.5 MM	4.25	11.50	yes	IIB
LA-IB-425-130	PRAMA IMPLANT HYBRID	D. 4.25 H. 13 MM	4.25	13.00	yes	IIB
LA-IB-425-150	PRAMA IMPLANT HYBRID	D. 4.25 H. 15 MM	4.25	15.00	yes	IIB
LA-IB-500-085	PRAMA IMPLANT HYBRID	D. 5.00 H. 8.5 MM	5.00	8.50	yes	IIB
LA-IB-500-100	PRAMA IMPLANT HYBRID	D. 5.00 H. 10 MM	5.00	10.00	yes	IIB
LA-IB-500-115	PRAMA IMPLANT HYBRID	D. 5.00 H. 11.5 MM	5.00	11.50	yes	IIB
LA-IB-500-130	PRAMA IMPLANT HYBRID	D. 5.00 H. 13 MM	5.00	13.00	yes	IIB
LA-IB-500-150	PRAMA IMPLANT HYBRID	D. 5.00 H. 15 MM	5.00	15.00	yes	IIB
LS-ZT-380-085	PRAMA RF IMPLANT ZIRTI	D. 3.80 H. 8.5 MM	3.80	8.50	yes	IIB
LS-ZT-380-100	PRAMA RF IMPLANT ZIRTI	D. 3.80 H. 10 MM	3.80	10.00	yes	IIB
LS-ZT-380-115	PRAMA RF IMPLANT ZIRTI	D. 3.80 H. 11.5 MM	3.80	11.50	yes	IIB



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LS-ZT-380-150	PRAMA RF IMPLANT ZIRTI	D. 3.80 H. 15 MM	3.80	15.00	yes	IIB
LS-ZT-425-085	PRAMA RF IMPLANT ZIRTI	D. 4.25 H. 8.50 MM	4.25	8.50	yes	IIB
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LS-ZT-425-150	PRAMA RF IMPLANT ZIRTI	D. 4.25 H. 15 MM	4.25	15.00	yes	IIB
LS-ZT-500-085	PRAMA RF IMPLANT ZIRTI	D. 5.00 H. 8.50 MM	5.00	8.50	yes	IIB
LS-ZT-500-100	PRAMA RF IMPLANT ZIRTI	D. 5.00 H. 10 MM	5.00	10.00	yes	IIB
LS-ZT-500-115	PRAMA RF IMPLANT ZIRTI	D. 5.00 H. 11.5 MM	5.00	11.50	yes	IIB
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LS-IB-500-150	PRAMA RF IMPLANT HYBRID	D. 5.00 H. 15 MM	5.00	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 KIWA CERMET 0476



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

Due Carrare May 19, 2016

