

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE



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TO WHOM IT MAY CONCERN

Our Ref. : **Declaration of Conformity DIATERMO - GIMA and relative accessories**

We

Name of manufacture: **LED SpA**

Country of origin: **ITALY**

Address/Tel/Fax: Via M.T. Cicerone 138 I-03100 FROSINONE / +39 0692870045 / +39 0692870046

Facility/ies (address): Via Selciatella 40 I-04011 APRILIA (LT) – ITALY (EUROPE)

Declare under our sole responsibility that quality of

Product Name	Product Code	GIMA Code	GMDN	Product Name	Product Code	GIMA Code	GMDN
DIATERMO 106	GMA10100.05	30516	44776	DIATERMO MB 132	GMA10300.10	30544	44776
DIATERMO 108	GMA10100.08	-	44776	DIATERMO MB 120 F	GMA10300.101	30631	44776
DIATERMO 50	GMA10100.051	30625	44776	DIATERMO MB 202	GMA10300.40	30456	44776
DIATERMO 80	GMA10100.081	30626	44776	DIATERMO MB 200 F	GMA10300.401	30633	44776
DIATERMO MB 80 D	GMA10100.101	30627	44776	DIATERMO MB 240	GMA10400.50	30690	44776
DIATERMO MB 122	GMA10100.20	30540/30538	44776	DIATERMO MB 250	GMA10400.70	30694	44776
DIATERMO MB 120 D	GMA10100.201	30628	44776	DIATERMO MB 380	GMA10400.60	30692	44776
DIATERMO MB 160	GMA10100.30	30541	44776	DIATERMO MB 300 D	GMA10400.801	30634	44776
DIATERMO MB 160 D	GMA10100.301	30629	44776	DIATERMO MB 400	GMA10400.90	30696	44776
DIATERMO MB 200	GMA10100.40	30542	44776	DIATERMO MB 400 D	GMA10400.901	30635	44776
DIATERMO MB 200 D	GMA10100.401	30630	44776	DIATERMO MB 300 T	GMA10400.T50	30695	44776
DIATERMO MB 200 T	GMA10400.T40	30693	44776	DIATERMO MB 400 T	GMA10400.T60	30697	44776

Classification:

EU Classification (Rule:9)	I	
	I*	
	IIa	
	IIb	X
	III	

Complies with all relevant requirements of:

■ Directive 93/42/EEC

(Annex: II)

Notified Body: 0051 (IMQ-Italy)

EC Certificate: 116/MDD

Applied standard(s):

Standard No	Title	Description
ISO 9001:15	Quality Management Systems	Quality System
EN ISO 13485:16	Quality Management Systems	Medical Device Quality System
EN 60601-1	MEDICAL ELECTRICAL EQUIPMENT – GENERAL STD.	General Requirement for Safety
EN 60601-1-2	MEDICAL ELECTRICAL EQUIPMENT – COLLATERAL STD.	Electromagnetic Compatibility – Requirement and test
EN 60601-2-2	MEDICAL ELECTRICAL EQUIPMENT – PARTICULAR STD.	Particular Requirement for the Safety of High Frequency Surgical Equipment
EN 60601-1-6	MEDICAL ELECTRICAL EQUIPMENT – COLLATERAL STD.	General requirements for basic safety and essential performance - Usability
EN 62304	MEDICAL DEVICES SOFTWARE.	Software life cycle processes

Valid until: 12/04/2022

Date/Signature/position/Stamp manufacture: 02/04/2020

LED SpA
P.IVA / Cof. P. 00704680602


Claudio Mauti - Quality Assurance Mgr.