LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

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TO WHOM IT MAY CONCERN

Our Ref. : ***Declaration of Conformity Magnetotherapy equipment and relative accessories GIMA***

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-04011APRILIA (LT) – ITALY (EUROPE)

Declare under our sole responsibility that quality of

Product Name	*Product Code*	*GIMA Code*	*GMDN*
MT BASE PLUS	GMA80200.10	28321	35169

Classification:

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

Digitally signed by Cosnicean Mihai
Date: 2023.08.04 18:16:36 EEST
Reason: MoldSign Signature
Location: Moldova

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 9001:08	Quality Managment Systems	Quality System
EN ISO 13485:12	Quality Managment 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 60601-1-6	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: 13/04/2017_____Quality Assurance Mgr.

LED SpA P.IVA/ Cod. Fiscale 00704660601