LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

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TO WHOM IT MAY CONCERN

Our Ref. : ***Declaration of Conformity System therapy 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*	*EAN 13 code*	*GMDN*
UTC2	GMASNR003	8023279283013	17908

Classification:

EU Classification (Rule:**9**)	I	
	I*	
	IIa	X
	IIb	
	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 Managment Systems	Quality System
EN ISO 13485:16	Quality Managment Systems	Medical Device Quality System
EN 60601-1	MEDICAL ELECTRICAL EQUIPMENT – GENERAL STD.	General Requirement for Safety
EN 60601-2-5	MEDICAL ELECTRICAL EQUIPMENT – PARTICULAR STD.	Particular Requirement for the Safety of ultrasonic physiotherapy equipment
EN 60601-2-10	MEDICAL ELECTRICAL EQUIPMENT – PARTICULAR STD.	Particular Requirement for the Safety of nerve and muscle stimulators
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: 02/07/2018 LED SpA P.IVA / Cod. Fiscale 00704680602 **Quality Assurance Mgr.**