

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

Sede Legale: Via Marco Tullio Cicerone 138 03100 FROSINONE (FR) ITALY

Sede Operativa: Via Selciatella, 40 – 04011 APRILIA (LT) ITALIA

Tel 06 92870045 - Fax 06 92870046

www.led.it e-mail info@led.it

EN
IE / MT

EU DECLARATION OF CONFORMITY (MDR 2017/745/UE)

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

It is declared the conformity with Regulation (EU) 2017/745 and the following Directives: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2) and Commission Delegated Directive (EU) 2015/863 of 31 March 2015.

This declaration of conformity is issued under the sole responsibility of LED SpA in compliance to Article 19 of EU MDR 2017/745. We hereby declare that the medical device specified under meet the provision of the Annex I of Regulation EU MDR 2017/745 for medical devices.

The declaration is based on:

- **Manufacturers Name** : LED SpA
- **Manufacturers Address** : Via Marco Tullio Cicerone 138 03100 FROSINONE (FR) ITALY
- **SRN (Single Registration Number)** : IT-MF-000012232
- **Basic UDI-DI** : 803363832 STE001 AB
- **Product Category**: Electrotherapy and ultrasound therapy equipment and related accessories
- **Name of the Device (s)** : see TABLE attached column

#

- **Product code** : see TABLE attached column

REF

- **Classification with rule number** : Class II a (Rule 9)
- **Conformity assessment route** : Annex IX Chapters I and III of Regulation (EU) 2017/745.
- **Intended use**: Active medical device and accessories for temporary and professional use, for combined therapy of ultrasound and/or therapeutic currents used for rehabilitative treatment of inflammatory conditions, post-traumatic states chronic and acute painful and conveying ionophoretic and sonophoretic of active ingredients.
- **Notified Body Name and address (code)** : IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A., Via Quintiliano 43 20138 Milano – ITALY, NB: 0051
- **Common Specification (CS)** : -
- **Identification of certificates issued** : EU certificate, 052 / MDR expiring 2027-09-21

Signature:



NAME: *Marco Mauti*

FUNCTION: *Legal Representative*

FROSINONE (FR) 03/07/2024

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IT - *ELENCO DISPOSITIVI* / EN - *LIST OF DEVICES*

Marca / Trade mark **GIMA**

	#		
1	UTC2	REF	GMASNR003
2.	GMAA35	REF	GMAA35
3.	GMA115	REF	GMA115