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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 ELT001 56
- **Product Category**: Electrotherapy equipments and electrostimulators and related Accessories
- **Name of the Device (s)** : see TABLE attached column

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- **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 short term use, for professional and home use in the healthcare environment, designed and made for electrotherapy applications for muscle toning and rehabilitative stimulation of painful chronic or post-traumatic syndromes and / or iontophoresis vehiculation of active ingredients for visceral physiotherapy.
- **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

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

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Marca / Trade mark **GIMA**

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1	Iono Base PLUS	REF	GMA80200.302
2	STIM BASE PLUS	REF	GMA80200.50
3	GMAC12	REF	GMAC12