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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 HFS001 44
- **Product Category**: High frequency surgical equipment
- **Name of the Device (s)** : see TABLE attached column 

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

REF
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- **Classification with rule number** : Class II b (Rule 9)
- **Conformity assessment route** : Annex IX Chapters I and III of Regulation (EU) 2017/745.
- **Intended use**: Medical device intended for temporary use for surgical operations in which cutting and/or coagulation of soft tissues is required, with a monopolar and/or bipolar technique, for survey minor and/or major in open and/or intra-operative percutaneous and/or endoscopic and/or laparoscopic.
- **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) 24.11.2023

# 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](http://www.led.it) e-mail [info@led.it](mailto:info@led.it)

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

Marca / Trade mark **GIMA**

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1	DIATERMO MB 300 D	REF	GMA10400.801
2	DIATERMO MB 300 T	REF	GMA10400.T50
3	DIATERMO MB 400 D	REF	GMA10400.901
4	DIATERMO MB 400 T	REF	GMA10400.T60
5	DIATERMO MB 200	REF	GMA10100.40
6	DIATERMO MB 200 F	REF	GMA10300.401
7	DIATERMO MB 200 D	REF	GMA10100.401
8	DIATERMO MB 200 T	REF	GMA10100.T40
9	DIATERMO MB 202	REF	GMA10300.40
10	DIATERMO 50	REF	GMA10100.051
11	DIATERMO 80	REF	GMA10100.081
12	DIATERMO 106	REF	GMA10100.05
13	DIATERMO 108	REF	GMA10100.08
14	DIATERMO MB 80 D	REF	GMA10100.101
15	DIATERMO MB 120 D	REF	GMA10100.201
16	DIATERMO MB 120 F	REF	GMA10300.101
17	DIATERMO MB 122	REF	GMA10100.20
18	DIATERMO MB 132	REF	GMA10300.10
19	DIATERMO MB 160	REF	GMA10100.30
20	DIATERMO MB 160 D	REF	GMA10100.301