

EU DECLARATION OF CONFORMITY - MDR 2017/745/UE -

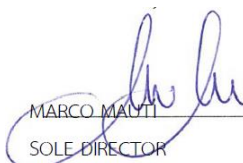
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

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 Selciatella 40 04011 Aprilia (LT) 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 #
Product code:	See TABLE attached column REF
Classification with rule number:	Class II b (Rule 9)
Conformity with 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):	<u>IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.</u> , Via Quintiliano 43 20138 Milano – ITALY, NB: 0051
Common Specification (CS):	-
Identification of certificates issued:	EU certificate, 052 / MDR expiring 2027-09-21


MARCO MAUTI
SOLE DIRECTOR
LED SpA

LED SpA
Marco Mauti
Sole Director

Aprilia (LT), 25.09.2025

EN - LIST OF DEVICES

Trade mark **GIMA**

	#	REF
1	DIATERMO MB 300 D	GMA10400.801
2	DIATERMO MB 300 T	GMA10400.T50
3	DIATERMO MB 400 D	GMA10400.901
4	DIATERMO MB 400 T	GMA10400.T60
5	DIATERMO MB 200	GMA10100.40
6	DIATERMO MB 200 F	GMA10300.401
7	DIATERMO MB 200 D	GMA10100.401
8	DIATERMO MB 200 T	GMA10100.T40
9	DIATERMO MB 202	GMA10300.40
10	DIATERMO 50	GMA10100.051
11	DIATERMO 80	GMA10100.081
12	DIATERMO 106	GMA10100.05
13	DIATERMO 108	GMA10100.08
14	DIATERMO MB 80 D	GMA10100.101
15	DIATERMO MB 120 D	GMA10100.201
16	DIATERMO MB 120 F	GMA10300.101
17	DIATERMO MB 122	GMA10100.20
18	DIATERMO MB 132	GMA10300.10
19	DIATERMO MB 160	GMA10100.30
20	DIATERMO MB 160 D	GMA10100.301
21	DIATERMO 50 T	GMA10100.T05
22	DIATERMO MB 120 T	GMA10100.T201



LED SpA
via Selciatella, 40
04011 Aprilia (LT) Italy

W led.it
M service@led.it
P +39 06 92870045

