

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

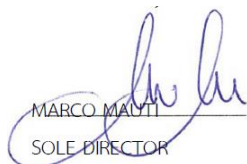
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

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 ESA0013E
Product Category:	Electrosurgical Accessories
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:	Devices destined to be connected, for temporary use, to high frequency electrosurgical units for surgical operations in which cutting and / or coagulation of soft tissues is required, with a monopolar and / or bipolar technique, for minor surgery and / or major in open and / or intra-operative percutaneous and / or endoscopic and / or laparoscopic. See attached table.
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 **LED**

#	REF					
PENCIL	00201.02 00206.00 00206.40					
PENCIL S	00205.00 00205.40		00420.00 00420.05			
CONNECTION	00402.00 00402.01 00402.02 00402.03 00402.04 00402.05	00404.02 00404.04 00404.08 00404.09 00404.10 00404.11	00411.00 00412.00 00413.00 00414.00 00415.00 00416.00 00417.00 00418.00			
NEUTRAL	00400.00 00401.00 00401.01 00401.02 00401.03 00401.10 00401.11 00401.12	00401.20 00401.21 00401.22 00403.01 00403.02	5365A 6429A			
ELECTRODE	00500.00 00500.00/L 00500.03 00500.D1 00500.D12 00500.D1/S 00500.D12/S	00500.L1 00500.L1/L 00500.L2 00500.L2/L 00500.L3 00500.L3/L 00500.L4 00500.L4/L 00500.L5 00500.L5/L 00500.L6 00500.L6/L 00500.L7 00500.L7/L 00500.L8 00500.L8/L 00500.L9 00500.L9/L 00500.L10 00500.L10/L 00500.S05 00500.S10 00500.S15	500500.D1/S 500500.D12/S 500500.L1 500500.L1/L 500500.L2 500500.L2/L 500500.L3 500500.L3/L 500500.L4 500500.L4/L 500500.L5 500500.L5/L 500500.L6 500500.L6/L 500500.L7 500500.L7/L 500500.L8 500500.L8/L 500500.L9 500500.L9/L 500500.L10 500500.L10/L	152-110 152-112 152-115 152-120 152-122 152-125 152-130 152-132 152-140 152-142 152-145 152-150 152-152 152-160 152-162 152-165	152-175-10 152-190-13 152-190-20 152-195	00420.10 00420.12 00420.14
BIPOLAR	110-700 110-750NS 110-755NS 110-760NS	310-110-05 310-112-05 310-140-10 310-140-20 310-142-10 310-142-20 310-180-10 310-180-20 310-182-10 310-185-10	310-510 310-550 310-590	410-100-15 410-100-19 410-200-18 410-200-21 410-200-23	500-300-00 510-000-00 510-000-00_L 510-300J01 510-300J02 510-300J03 510-300J04 510-300J05 510-300J06 510-300J07 510-300-10 510-300-20 510-300-30 510-300-40 510-300-50 510-300-10_L 510-300-20_L 510-300-30_L 510-300-40_L 510-300-50_L	
MONOPOLAR	330-134-20 330-160					



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

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

