

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** : 803363832ESA0013E
- **Product Category**: Electrosurgical accessories
- **Name of the Device (s)** : see TABLE attached column
- **Product code** : see TABLE attached column
- **Classification with rule number** : Class II b (Rule 9)
- **Conformity assessment route** : Annex IX, Conformity assessment based on a quality management system and on assessment of technical documentation
- **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)** : IMQ S.p.A. Via Quintiliano 43 20138 Milano - ITALY (0051)
- **Harmonized Standards** : EN ISO 13485:2016/A11:2021 / EN ISO 14971:2019/A11:2021 / EN 60601-1:2006/A2:2020 / EN 60601-2-2:2018 / EN 60601-1-6:2015/A2:2020 / EN 62366-1:2015/A1:2020 / EN ISO 15223-1:2021 / EN ISO 20417:2021/ EN ISO 10993-1:2020 / EN ISO 10993-5:2009 / EN ISO 10993-10:2013 / EN ISO 10993-11:2018 / EN ISO 10993-23:2021/ EN ISO 17664-1:2021/ EN ISO 17665-1:2006 / EN ISO 11138-1: 2017
- **Common Specification (CS)** : -
- **Identification of certificates issued** : EU certificate, 052 / MDR expiring 2027-09-21

Signature:



FUNCTION: *Legal Representative*

NAME: *Marco Mauti*

FROSINONE (FR) 22.07.2024

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

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IT - ELENCO DISPOSITIVI / EN - LIST OF DEVICES

Marca / Trade mark **LED**

#											
PENCIL	REF	00201.02	00206.00	00206.40							
PENCIL S	REF	00205.00	00205.40	00420.00	00420.05						
CONNECTION	REF	00402.00	00402.01	00402.02	00402.03	00402.04	00402.05	00404.02	00404.04	00404.08	00404.09
	REF	00404.10	00404.11	00411.00	00412.00	00413.00	00414.00	00415.00	00416.00	00417.00	00418.00
NEUTRAL	REF	00400.00	00401.00	00401.01	00401.02	00401.03	00401.10	00401.11	00401.12	00401.20	00401.21
	REF	00401.22	00403.01	00403.02	5365A	6429A					
ELECTRODE	REF	00500.00	00500.00/L	00500.03	00500.D1	00500.D12	00500.D1/S	00500.D12/S	00500.L1	00500.L1/L	00500.L2
	REF	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
	REF	00500.L7/L	00500.L8	00500.L8/L	00500.L9	00500.L9/L	00500.L10	00500.L10/L	00500.S05	00500.S10	00500.S15
	REF	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
	REF	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
	REF	500500.L10	500500.L10/L	152-110	152-112	152-115	152-120	152-122	152-125	152-130	152-132
	REF	152-140	152-142	152-145	152-150	152-152	152-160	152-162	152-165	152-175-10	152-190-13
	REF	152-190-20	152-195	00420.10	00420.12	00420.14					
BIPOLAR	REF	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
	REF	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
	REF	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
	REF	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
	REF	510-300-40_L	510-300-50_L								
MONOPOLAR	REF	330-134-20	330-160								

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Marca / Trade mark **SURGEON**

#											
PENCIL	REF	00201.02_S	00206.00_S	00206.40_S							
PENCIL S	REF	00205.00_S	00205.40_S	00420.00_S	00420.05_S						
CONNECTION	REF	00402.00_S	00402.01_S	00402.02_S	00402.03_S	00402.04_S	00402.05_S	00404.02_S	00404.04_S	00404.08_S	00404.09_S
	REF	00404.10_S	00404.11_S	00411.00_S	00412.00_S	00413.00_S	00414.00_S	00415.00_S	00416.00_S	00417.00_S	00418.00_S
NEUTRAL	REF	00400.00_S	00401.00_S	00401.01_S	00401.02_S	00401.03_S	00401.10_S	00401.11_S	00401.12_S	00401.20_S	00401.21_S
	REF	00401.22_S	00403.01_S	00403.02_S							
ELECTRODE	REF	152-110_S	152-112_S	152-115_S	152-120_S	152-122_S	152-125_S	152-130_S	152-132_S	152-140_S	152-142_S
	REF	152-145_S	152-150_S	152-152_S	152-160_S	152-162_S	152-165_S	152-175-10_S	152-190-13_S	152-190-20_S	152-195_S
	REF	00420.10_S	00420.12_S	00420.14_S							
BIPOLAR	REF	110-700_S	110-750NS_S	110-755NS_S	110-760NS_S	310-110-05_S	310-112-05_S	310-140-10_S	310-140-20_S	310-142-10_S	310-142-20_S
	REF	310-180-10_S	310-180-20_S	310-182-10_S	310-185-10_S	310-510_S	310-550_S	310-590_S	410-100-15_S	410-100-19_S	410-200-18_S
	REF	410-200-21_S	410-200-23_S	510-000-00_S	510-300-10_S	510-300-20_S	510-300-30_S	510-300-40_S	510-300-50_S		
MONOPOLAR	REF	330-134-20_S	330-160_S								