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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

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** : 803363832HFS00144
- **Product Category**: High frequency surgical equipment
- **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
- **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 60601-1:2006/A2:2020 / EN 60601-2-2:2018 / EN 60601-1-2:2015/A1:2020 / EN 60601-1-6:2015/A2:2020 / EN 62304:2006/A1:2015 / EN ISO 14971:2019
- **Common Specification (CS)** : -
- **Identification of certificates issued** : EU certificate, 052 / MDR expiring 2027-09-21

Signature:

LED SpA  
P.IVA / Cod. Fiscale  
00704980602



NAME: Marco Mauti

FUNCTION: Legal Representative

FROSINONE (FR) 22.09.2022

EU Declaration: 10f-MDR\_HSF001\_0\_EN

IT - **ELENCO DISPOSITIVI** / EN - **LIST OF DEVICES** / FR - **LISTE DES APPAREILS** / BG - **СПИСЪК НА УСТРОЙСТВАТА** / CS - **SEZNAM ZAŘÍZENÍ** / DA - **LISTE OVER ENHEDER** / DE - **LISTE DER GERÄTE** / ET - **SEADMETE LOETELU** / GA - **LIOSTA NA bhFEISTÍ** / EL - **ΚΑΤΑΛΟΓΟΣ ΣΥΣΚΕΥΩΝ** / ES - **LISTA DE DISPOSITIVOS** / HR - **POPIS UREĐAJA** / LV - **IERĪĀU SARAKSTS** / LT - **ĮRENGINIŲ SĄRAŠAS** / HU - **AZ ESZKÖZÖK LISTÁJA** / MT - **LISTA TA' APPARATI** / NL - **LIJST MET APPARATEN** / PL - **LISTA URZĄDZEŃ** / PT - **LISTA DE DISPOSITIVOS** / RO - **LISTA DISPOZITIVELOR** / SL - **SEZNAM NAPRAV** / SK - **ZOZNAM ZARIADENÍ** / FI - **LUETTELO LAITTEISTA** / SV - **ISTA ÖVER ENHETER**

Marca / Trade mark / Marque / Mapka / Značka / Mærke / Marke / Bränd / Branda / Μάρκα / Marca / Marka / Zīmols / Prekės ženklas / Márka / Brand / Merk / Marka / Marca / Marca / Znamka / Značka / Brändi / varumärke **LED**

	#	REF	UDI
1	<b>SURTRON TOUCH HP 400</b>	10400.T902	8033638324424
2	<b>SURTRON 300 HP</b>	10400.801 / 10800.902	8033638321188
3	<b>SURTRON 400 HP</b>	10400.901 / 10400.902	8033638321904
4	<b>SURTRON TOUCH 240</b>	10400.T50	8033638321195
5	<b>SURTRON TOUCH 300</b>	10400.T80	8033638321911
6	<b>SURTRON TOUCH 380</b>	10400.T60	8033638324929
7	<b>SURTRON TOUCH 400</b>	10400.T90	8033638324455
8	<b>SURTRON TOUCH HP 300</b>	10400.T802	8033638324943
9	<b>SURTRON SB</b>	10900.201	8033638324448
10	<b>SURTRON TOUCH 200</b>	10100.T40	8033638322970
11	<b>SURTRON 200</b>	10100.401	8033638321140
12	<b>SURTRON FLASH 200</b>	10300.401	8033638321171
13	<b>SURTRON TOUCH HP 200</b>	10100.T402	8033638325377
14	<b>SURTRON TOUCH PL</b>	10100.P402	8033638325384
15	<b>SURTRON 160</b>	10100.301	8033638321133
16	<b>SURTRON 50</b>	10100.071	8033638324417
17	<b>SURTRON 50D</b>	10100.051	8033638321096
18	<b>SURTRON 80</b>	10100.101	8033638321119
19	<b>SURTRON 80D</b>	10100.081	8033638321102
20	<b>SURTRON 120</b>	10100.201	8033638321126
21	<b>SURTRON FLASH 120</b>	10300.101	8033638321157
22	<b>SURTRON FLASH 160 HF</b>	10300.201	8033638321164
23	<b>SURTRON TOUCH HP 50D</b>	10100.T05	8033638325391
24	<b>SURTRON TOUCH HP 80D</b>	10100.T08	8033638325407