

## 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:

|   |   |
|---|---|
| <b>Manufacturers Name:</b>                    | LED SpA   |
| <b>Manufacturers Address:</b>                 | Via Selciatella, 40 04011 APRILIA (LT) ITALY                |
| <b>SRN (Single Registration Number):</b>      | IT-MF-000012232   |
| <b>Basic UDI-DI:</b>                          | 803363832 SEE00156  |
| <b>Product Category:</b>                      | Surgical smoke evacuation equipment                         |
| <b>Name of the Device(s):</b>                 | See TABLE attached column <b>#</b>                          |
| <b>Product code:</b>                          | See TABLE attached column <b>REF</b>                        |
| <b>Classification with rule number:</b>       | Class I (Rule 1)  |
| <b>Conformity with assessment route:</b>      | Preparation of the technical documentation Annex II and III |
| <b>Notified Body Name and address (code):</b> | -   |
| <b>Common Specification (CS):</b>             | -   |
| <b>Identification of certificates issued:</b> | -   |
| <b>GMDN code:</b>                             | 36686   |

  
MARCO MAUTI  
SOLE DIRECTOR  
LED SpA

LED SpA  
Marco Mauti  
Sole Director

Aprilia (LT), 20.08.2025

## EN - LIST OF DEVICES

Trade mark **LED**

|    | #                            | REF           |
|----|------------------------------|---------------|
| 1  | <b>SURTRON TOUCH HP EVAC</b> | 10200.T10     |
| 2  | <b>SURTRON EVAC</b>          | 10200.10      |
| 3  | <b>SURTRON EVAC</b>          | 10200.10/115V |
| 4  | <b>00900.01</b>              | 00900.01      |
| 5  | <b>00900.01/12</b>           | 00900.01/12   |
| 6  | <b>00900.02</b>              | 00900.02      |
| 7  | <b>00900.02/06</b>           | 00900.02/06   |
| 8  | <b>00900.03</b>              | 00900.03      |
| 9  | <b>00900.04</b>              | 00900.04      |
| 10 | <b>00900.05</b>              | 00900.05      |
| 11 | <b>00900.06</b>              | 00900.06      |
| 12 | <b>00900.06/06</b>           | 00900.06/06   |
| 13 | <b>00900.07</b>              | 00900.07      |
| 14 | <b>00900.08/12</b>           | 00900.08/12   |
| 15 | <b>00900.FU01</b>            | 00900.FU01    |
| 16 | <b>00900.FU01/10</b>         | 00900.FU01/10 |
| 17 | <b>00900.FH01</b>            | 00900.FH01    |
| 18 | <b>00900.FST</b>             | 00900.FST     |
| 19 | <b>00900.FST/10</b>          | 00900.FST/10  |
| 20 | <b>00901.FST</b>             | 00901.FST     |
| 21 | <b>00901.FU01</b>            | 00901.FU01    |



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