

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE

Legal Address: Via Marco Tullio Cicerone 138 03100 FROSINONE (FR) ITALY

Operative Address: Via Selciatella, 40 – 04011 APRILIA (LT) ITALIA

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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

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** : 803363832SEE00156
- **Product Category**: Surgical evacuation equipment
- **Name of the Device (s)** : see TABLE attached column

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- **Product code** : see TABLE attached column

REF

- **Classification with rule number** : Class I (Rule 1)
- **Conformity assessment route** : Preparation of the technical documentation Annex II and III
- **Notified Body Name and address (code)** : -
- **Common Specification (CS)** : -
- **Identification of certificates issued** : -

Signature:



NAME: *Marco Mauti*

FUNCTION: *Legal Representative*

FROSINONE (FR) 24.07.2024

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IT - *ELENCO DISPOSITIVI E ACCESSORI* / EN - *LIST OF DEVICES AND ACCESSORIES*

Marca / Trade mark **LED**

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1	SMOKE EVACUATOR	REF	GMA10200.10