

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE



Via Selciatella, 40 – 04011 APRILIA (LT) ITALIA

Tel +39 06 92870045

Fax +39 06 92870046

www.led.it e-mail info@led.it

TO WHOM IT MAY CONCERN

Our Ref. : *Declaration of Conformity Accessories for smoke evacuator – EVAC smoke evacuation tubes*

We

Name of manufacture: **LED SpA**

Country of origin: **ITALY**

Address/Tel/Fax: Via M.T. Cicerone 138 I-03100 FROSINONE / +39 0692870045 / +39 0692870046

Facility/ies (address): Via Selciatella 40 I-04011 APRILIA (LT) – ITALY (EUROPE)

Declare under our sole responsibility that quality of

Product Name	Type	REF				
Tubi aspirazione fumi EVAC EVAC smoke evacuation tubes	STERILE ETO*	REF 00900.01 EAN13 8033638321348	00900.01/12 12x 8033638321348	00900.03 8033638323328	00900.03/06 6x 8033638323328	
	NO STERILE	REF 00900.02 EAN13 8033638321355	00900.02/06 6x 8033638321355	00900.06 8033638321560	00900.06/06 6x 8033638321560	
	AUTOCLAVABLE	REF 00900.04 EAN13 8033638321553	00900.05 8033638321546	00900.07 8033638321577		

Classification:

EU Classification (Rule:1)	I	X
	I*	X
	IIa	
	IIb	
	III	

Complies with all relevant requirements of:

■ Directive 93/42/EEC

(Annex: II-VII)

*Notified Body: 0051 (IMQ-Italy)

*EC Certificate: 116/MDD

Applied standard(s):

Standard No	Title	Description
ISO 9001:08	Quality Management Systems	Quality System
EN ISO 13485:12	Quality Management Systems	Medical Device Quality System
*EN 556-1	STERILIZATION OF MEDICAL DEVICES	Requirements for medical devices to be designated "STERILE"
EN 1041	MEDICAL DEVICES	Information supplied by the manufacturer of medical devices
EN 15223-1	MEDICAL DEVICES	Symbols to use on labels and information to be supplied. General requirements

Valid until: 12/04/2022

Date/Signature/position/Stamp manufacture: 13/04/2017

LED SpA
P.IVA / Cod. Fiscale
00709880602

Quality Assurance Mgr.