

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 filters*

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-04011APRILIA (LT) – ITALY (EUROPE)

Declare under our sole responsibility that quality of

Product Name	Description	REF		
Filtri aspirazione fumi EVAC	Ulpa Filter 5 h - BLU	REF	00900.FST	00900.FST/10
		EAN13	8033638321362	8033638324332
EVAC smoke evacuation filters	Ulpa Filter 20 h - RED	REF	00900.FU01	00900.FU01/10
		EAN13	8033638321379	8033638324349

Classification:

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

Complies with all relevant requirements of:

■ Directive 93/42/EEC

(Annex: VII)

Applied standard(s):

Standard No	Title	Description
ISO 9001:15	Quality Management Systems	Quality System
EN ISO 13485:16	Quality Management Systems	Medical Device Quality System
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: 02/07/2018

LED SpA
P.IVA Col. Fiscale
00704680606

Quality Assurance Mgr.