

LED SpA

PROGETTAZIONI E PRODUZIONI ELETTRONICHE



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TO WHOM IT MAY CONCERN

Our Ref. : **Declaration of Conformity Foot switch – Accessory: Holder, Adapter/Selector**

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	00304.00	00304.01	00304.02	00304.04	00304.PO		
Foot switch	Single	Descr.	Water-proof foot switch (5 pin)	Water-proof foot switch (3pin)	Water-proof foot switch(5 pin) physio	Water-proof foot switch (5 pin) 3 mt	Protection for single foot switch		
		EAN13	8033638321591	8033638321614	8033638324370	8033638321607	8033638324363		
Foot switch	Double	REF	00305.01	00305.03	00305.04	00305.05	00305.06	00306.03	00306.06
		Descr.	HP240-380 double water-proof foot switch	Double water-proof foot switch	HP300-400 double water-proof foot switch	SB Double water-proof foot switch	TOUCH HP300-400 double water-proof foot switch	Double water-proof foot switch with selector	TOUCH HP300-400 double water-proof foot switch with selector
		EAN13	8033638321652	8033638321638	8033638321621	8033638321645	8033638325124	8033638325131	8033638325148

Product Name	Type	REF	00201.03	00202.00			
Accessory	Holder	Descr.	Microsurgical handle holder	Holder for Handle and Electrodes			
		EAN13	8033638321362	8033638322697			
Accessory	Adpter Selector	REF	00498.00	00498.04	00498.06	00498.08	00498.10
		Descr.	Selector for the bipolar modality	2001 bipolar adapter selector (until 2009)	Adapter for neutral electrode 6,3mm/val	Bipolar Adapter EUR/2xM2.5	Bipolar Adapter EUR/3xM4
		EAN13	8033638321867	8033638322260	8033638324387	8033638320000	8033638320000

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 60601-1	MEDICAL ELECTRICAL EQUIPMENT – GENERAL STD.	General Requirement for Safety
EN 60601-2-2	MEDICAL ELECTRICAL EQUIPMENT – PARTICULAR STD.	Particular Requirement for the Safety of High Frequency Surgical Equipment

Valid until: 12/04/2022

Date/Signature/position/Stamp manufacture: 01/07/2019



Quality Assurance Mgr.