



EU DECLARATION OF CONFORMITY according to Regulation (EU) 2017/745

EN

Manufacturer:	FIAB SpA
Registered address:	Via Costoli 4, 50039 Vicchio (FI), Italia
Single Registration Number:	IT-MF-000005988
Basic UDI-DI:	803300326206000004NK
Product name/ Intended Purpose	Sterile disposable cleaning pad for electrosurgery
Models:	See list in Attachment
Technical Documentation File	TDF 206
Risk Class (MDR Annex VIII):	IS
Conformity assessment procedure performed:	Annex IX – Conformity assessment based on a quality management system (Chapter I)
Notified Body	BSI Group The Netherlands B.V. 2797
Certificate(s) issued	EU quality management system certificate MDR 747884 R000
Technical standards and/or Common Specifications applied:	EN 1041 [2008/A1:2013] - EN 556-1 [2001/AC:2010] - EN ISO 10993-1 [2018] - EN ISO 11135 [2014] - EN ISO 13485 [2016] - EN ISO 14971 [2019] - EN ISO 15223-1[2020]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we hereby declare

- that the medical devices specified meet the provision of the Regulation (EU) 2017/745 for medical devices
- that the procedures of FIAB quality management system according to ISO 13485 have been followed, Certificate of Registration no.MD77846 issued by BSI
- that the products do not contain medicinal substances, elements of animal origin or their derivatives, human blood derivatives, and are latex free

Signature: _____

Vicchio, 02/12/2021

Alberto Calabrò
Managing Director

Declaration Code	EU-00000224-206	First issued:	19/11/2021
Cod	99500201MD4A	Last revised:	02/12/2021

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Attachment of EU Declaration of Conformity – List of models

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