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

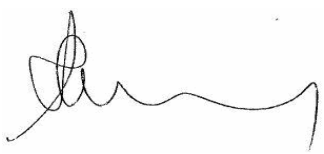
EN

Manufacturer:	FIAB SpA
Registered address:	Via Costoli 4, 50039 Vicchio (FI), Italia
Single Registration Number:	IT - MF - 000005988
Basic UDI-DI:	803300326007000002MJ
Product name:	Reusable electrocautery
Intended Purpose:	Cauterisation of tissues and small blood vessels during surgical operations. No high frequency generator is required
Models:	See list in Attachment
Technical Documentation File:	TDF 007
Risk Class (MDR Annex VIII):	IIB
Conformity assessment procedure performed:	Annex IX - Chapter I and Chapter III
Notified Body:	BSI Group The Netherlands B.V. 2797
Certificate(s) issued:	EU quality management system certificate: MDR 747884 R00
Technical standards and/or Common Specifications applied:	EN ISO 10993-1 [2020], EN ISO 13485 [2016], EN ISO 14971 [2019], EN ISO 15223-1 [2021], EN ISO 20417 [2021], EN 60601-1[2006/A1+A12+A2]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we herby 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
- are latex free

Signature



Alberto Calabrò
Managing Director

Vicchio, 01/04/2025

Declaration Code	EU-007000002-007-1	First issued:	01/04/2025
Cod 99500201MD4B		Last revised:	01/04/2025

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Attachment of EU Declaration of Conformity - List of models

F7297, F7299

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