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

EN

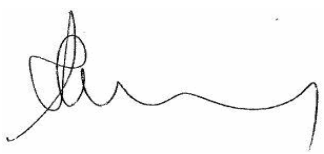
Manufacturer:	FIAB SpA
Registered address:	Via Costoli 4, 50039 Vicchio (FI), Italia
Single Registration Number:	IT - MF - 000005988
Basic UDI-DI:	8033003260060000001LX
Product name:	Disposable sterile pencil for electrosurgery
Intended Purpose:	Tissue cut and coagulation, during an electrosurgical procedure, using a compatible high-frequency generator
Models:	See list in Attachment
Technical Documentation File:	TDF 006
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 R000
Technical standards and/or Common Specifications applied:	EN ISO 10993-1 [2020], EN ISO 13485 [2016/A11:2021], EN ISO 14971 [2019/A11:2021], EN ISO 15223-1 [2021], EN ISO 20417 [2021], EN 556-1 [2024], EN 60601-1 [2006]+A1+A12+A2 [2021], EN IEC 60601-2-2 [2018], EN ISO 11135 [2014/A1:2019], EN ISO 11607-1 [2020/A1:2023], EN ISO 11607-2 [2020/A1:2023]

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, 23/01/2026

Declaration Code	EU-006000001-006-2	First issued:	07/01/2026
Cod 99500201MD4C		Last revised:	23/01/2026

bsi ISO 13485 Quality Management Systems CERTIFIED
MD 77846

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Attachment of EU Declaration of Conformity - List of models

F4390, F4390/4M, F4390/4M/A, F4390/4M/FR, F4390/4MTEF, F4390/5, F4390/5/FR, F4390/5WB, F4390/A, F4390/AL, F4390/FR, F4390/L, F4390/P, F4390/PL, F4390/WB, F4390TEF, F4795, F4795/5, F4795/5TEF, F4795TEF, F4796, F4796/5, F4797, F4797/5, F4797/5/FR, F4797/5A, F4797/5ERB, F4797/5L, F4797/5P/ERB, F4797/5TEF, F4797/5TEF/FR, F4797/5WB, F4797/A, F4797/A/ERB, F4797/AL, F4797/AS, F4797/ATEF, F4797/ERB, F4797/ERB/FR, F4797/ERB-ET, F4797/FR, F4797/L, F4797/P, F4797/P/ERB, F4797/PL, F4797/TEF, F4797/WB, F4797SE, F4797SE/4048S, F4797SE/5, F4797SE/5TEF, F4797SE/TEF, F4797SE/WB, F4797T, F4797TEF, F4797TEF/FR, F4798, F4798/5, F4798/ERB, F4798SE/5TEF, F4798SE/ATEF, F4798SE/TEF, F4799

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