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

EN

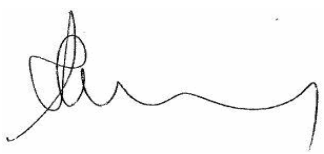
Manufacturer:	FIAB SpA
Registered address:	Via Costoli 4, 50039 Vicchio (FI), Italia
Single Registration Number:	IT - MF - 000005988
Basic UDI-DI:	803300326006000009MF
Product name:	Sterile disposable extension for electrosurgery
Intended Purpose:	Tissue cut and coagulation, during an electrosurgical 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-006000009-006-2	First issued:	07/01/2026
Cod 99500201MD4C		Last revised:	23/01/2026

bsi ISO 13485 Quality Management Systems CERTIFIED
MD 77846

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

EN

Attachment of EU Declaration of Conformity - List of models

F4902, F4903, F4904O

Declaration Code	EU-006000009-006-2	First issued:	07/01/2026
Cod 99500201MD4C		Last revised:	23/01/2026

FIAB SpA – 50039 Vicchio - Firenze - Italia
Sede legale: Via P. Costoli, 4 - Logistica: Via Meglini, 2-4
Unità operative: Via Passerini, 2-3-4-6 – Via della Resistenza, 18
Tel. +39 0558497999 - Fax +39 0558497979 - www.fiab.it
Cap. Soc. int. vers. 2.000.000,00 € - C.F.-P.I. e n. Reg. Imp. FI 01835220482 - Trib. FI. n.33541
C.C.I.A.A. FI n. 339066 REA - c/c postale 14476501 - EUROPEAN VAT: IT 01835220482

bsi ISO 13485 Quality Management Systems CERTIFIED
MD 77846