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

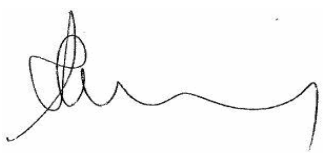
EN

Manufacturer:	FIAB SpA
Registered address:	Via Costoli 4, 50039 Vicchio (FI), Italia
Single Registration Number:	IT - MF - 000005988
Basic UDI-DI:	8033003260060000007MB
Product name:	Sterile disposable electrosurgery electrode
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-006000007-006-2	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

F4042/TU, F4044, F4044/TEF, F4044T, F4046, F4046/6TEF, F4046/S, F4046/TEF, F4046/TEF/FR, F4046S/TEF, F4046T, F4047/TU, F4047/TU/FR, F4048, F4048/S, F4048/TEF, F4048/TEF/FR, F4048/TU, F4048S/TEF, F4048S/TEF100, F4048T, F4049, F4050, F4050/16TEF, F4050/S, F4050/TEF, F4050/TEF/FR, F4050S/16TEF, F4050S/TEF, F4050T, F4051/45TU, F4051/TU, F4051/TU108, F4051/TU75, F4052, F4052/S, F4052/TEF, F4052T, F4053, F4053/TEF, F4053S/TEF, F4067, F4067/3, F4067/5, F4067/TEF, F4067T, F4620, F4621, F4622, F4623, F4624, F4625, F4626, F4630, F4631, F4632, F4640, F4641, F4642

Declaration Code	EU-006000007-006-2	First issued:	07/01/2026
Cod 99500201MD4C		Last revised:	23/01/2026

bsi ISO 13485 Quality Management Systems CERTIFIED
MD 77846