# *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:** | 803300326006000011M2 |
| **Product name:** | Reusable 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.<br>2797 |
| **Certificate(s) issued:** | EU quality management system certificate:<br>MDR 747884 |
| **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/A1:2025], EN ISO 20417 [2026], EN 60601-1 [2006/A13:2024], EN IEC 60601-2-2 [2018] |

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, 10/06/2026

| | | | |
|---|---|---|---|
| Declaration Code | EU-006000011-006-2 | First issued: | 03/06/2026 |
| Cod 99500201MD4C | | Last revised: | 10/06/2026 |



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**

F4141, F4141/ERB, F4151, F4242, F4243, F4244, F4246, F4252, F4254, F4256, F4814

| | | | |
|---|---|---|---|
| Declaration Code | EU-006000011-006-2 | First issued: | 03/06/2026 |
| Cod 99500201MD4C | | Last revised: | 10/06/2026 |

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