



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: 803300326007000003ML

Product name: Disposable sterile 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 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 60601-1-2 [2015/A1:2021], EN ISO 11135 [2014/A1:2019]

With this Declaration of Conformity, issued under the sole responsibility of FIAB SpA as the Manufacturer, we hereby 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, 29/08/2025

Declaration Code EU-007000003-007-3

Cod 99500201MD4C

First issued: 01/04/2025

Last revised: 29/08/2025



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

EN

Attachment of EU Declaration of Conformity - List of models

F7234, F7234/1, F7244, F7244/1, F7255, F7255/1, F7255UF, F7266, F7277, F7288, F7288/1

Declaration Code EU-007000003-007-3

Cod 99500201MD4C

First issued: 01/04/2025

Last revised: 29/08/2025