



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: 803300326008000001MZ

Product name: Reusable electrodes for ECG

Intended Purpose: Surface ECG recording

Models: See list in Attachment

Technical Documentation File: TDF 008

Risk Class (MDR Annex VIII): I

Conformity assessment procedure performed: Annex IV (EU Declaration of Conformity)

**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 60601-1 [2006]+A1+A12+A2 [2021]

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, 22/08/2025

Declaration Code EU-008000001-008-5
Cod 99500038MD4B

First issued: 26/05/2021
Last revised: 22/08/2025



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Attachment of EU Declaration of Conformity - List of models

F9002NI, F9002SSC, F9003NI, F9003SSC, F9007, F9007P, F9007PL, F9008PLUS, F9008SSC, F9009NI, F9009PLUS, F9009SSC, F9009ULTRA, F9010PSSC, F9010SSC, F9010SSC-6, F9016PLUS, F9016SSC, F9016ULTRA, F9023NI, F9023PLUS, F9023SSC, F9024CSSC, F9024NI, F9024OSSC, F9024SSC, F9024SSC2W, F9024SSCGI, F9024SSCNE, F9024SSCRG, F9024SSCRO, F9024SSCVE, F9024ULTRA

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