



## 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 13485 [2016], EN ISO 14971 [2019], EN ISO 15223-1 [2021], EN ISO 20417 [2021], EN 60601-1[2006/A1+A12+A2]

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, 25/11/2024

Declaration Code EU-008000001-008-2  
Cod 99500038MD4B

First issued: 26/05/2021  
Last revised: 15/11/2024



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

EN

### **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, F9024SSCGI, F9024SSCNE, F9024SSCRG, F9024SSCRO, F9024SSCVE, F9024ULTRA

Declaration Code EU-008000001-008-2

Cod 99500038MD4B

First issued: 26/05/2021

Last revised: 15/11/2024