



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

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**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 Calabò  
Managing Director

Vicchio, 25/11/2024

Declaration Code	EU-008000001-008-2	First issued:	26/05/2021
Cod 99500038MD4B		Last revised:	15/11/2024



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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, F9024SSCGI, F9024SSCNE, F9024SSCRG, F9024SSCRO, F9024SSCVE, F9024ULTRA

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