



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

### EN

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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:   | 803300326206000004NK  |
| Product name/ Intended Purpose                            | Sterile disposable cleaning pad for electrosurgery  |
| Models:   | See list in Attachment  |
| Technical Documentation File                              | TDF 206   |
| Risk Class (MDR Annex VIII):                              | IS  |
| Conformity assessment procedure performed:                | Annex IX – Conformity assessment based on a quality management system (Chapter I)   |
| 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 556-1 [2001/AC:2010] - EN ISO 10993-1[2020] - EN ISO 11135 [2014] - EN ISO 13485 [2016] - EN ISO 14971 [2019] - EN ISO 15223-1[2021] - EN ISO 20417 [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, and are latex free

Signature:

Vicchio, 10/11/2022

Alberto Calabrò  
Managing Director

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|------------------|-----------------|---------------|------------|
| Declaration Code | EU-00000455-206 | First issued: | 19/11/2021 |
| Cod              | 99500201MD4A    | Last revised: | 10/11/2022 |

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Attachment of EU Declaration of Conformity – List of models

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