



## 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:** 803300326130000007LM

**Product name:** Ultrasound transmission and IPL transparent gel

**Intended Purpose:** High conductivity transmission gel for ultrasound and IPL

**Models:** See list in Attachment

**Technical Documentation File:** TDF 130

**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], 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
- are latex free

Signature

Alberto Calabrò  
Managing Director

Vicchio, 24/09/2024

Declaration Code EU-130000007-130-1  
Cod 99500038MD4B

First issued: 03/06/2021  
Last revised: 24/09/2024



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**Attachment of EU Declaration of Conformity - List of models**

G002, G008, G0084, G009, G010

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