



## 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: 803300326708000005TA

Product name/ Intended Purpose: Fastening elastic belts

Models: See list in Attachment

Technical Documentation File: TDF 708

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, and are latex free

Signature:

Vicchio, 12/01/2023

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Alberto Calabrò  
Managing Director

Declaration Code EU-00000475-708

First issued: 28/06/2021

Last revised: 10/11/2022

Cod 99500038MD4B



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### Attachment of EU Declaration of Conformity – List of models

00451 - 00453 - 00794
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