



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:

Alberto Calabò
Managing Director

Vicchio, 12/01/2023

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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