



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:	803300326708000002T4
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, 27/07/2023

Alberto Calabrò
Managing Director

Declaration Code EU-00000536-708

First issued: 10/06/2021

Last revised: 27/07/2023

Cod 99500038MD4B

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Attachment of EU Declaration of Conformity – List of models

PG935/10 - PG935/10M - PG935/12 - PG935/15 - PG935/15M - PG935/3 - PG935/3M - PG935/4 - PG935/4M - PG935/6 - PG935/6M - PG935/7 - PG935/8 - PG935/8M - PG936/10 - PG936/4 - PG936/6 - PG936/8 - PG937/10 - PG937/5 - PG937/6M - PG943/10 - PG943/10M - PG943/15 - PG943/15M - PG943/4 - PG943/4M - PG943/6 - PG943/6M - PG943/8 - PG943/8M - PG945/10 - PG945/10-1 - PG945/10-2 - PG945/10-3 - PG945/10M - PG945/12 - PG945/12-1 - PG945/15 - PG945/15M - PG945/3 - PG945/3M - PG945/4 - PG945/4-1 - PG945/4M - PG945/6 - PG945/6-1 - PG945/6-2 - PG945/6M - PG945/8 - PG945/8-1 - PG945/8M - PG946/10 - PG946/10M2 - PG946/15 - PG946/2M2 - PG946/4 - PG946/6 - PG946/6M2 - PG946/8 - PG946/8M2 - PG947/5 - PG947/6 - PG948/10 - PG948/10M - PG948/4 - PG948/4M - PG948/5MF - PG948/6 - PG948/6M - PG948/8 - PG948/8M - PG955/10 - PG955/10-2 - PG955/10M - PG955/12 - PG955/15 - PG955/15-2 - PG955/15M - PG955/3 - PG955/3M - PG955/4 - PG955/4M - PG955/6 - PG955/6M - PG955/8 - PG955/8M - PG965/10 - PG965/10M - PG965/15 - PG965/15M - PG965/3 - PG965/3M - PG965/4 - PG965/4M - PG965/6 - PG965/6-2 - PG965/6M - PG965/8 - PG965/8-2 - PG965/8M - PG965GR/025 - PG977/10 - PG977/10M - PG977/15 - PG977/15M - PG977/3 - PG977/3M - PG977/4 - PG977/4M - PG977/6 - PG977/6M - PG977/8 - PG977/8M - PG978/10M - PG978/4M - PG978/6M - PG978/8M - PG985/4 - PG985/6 - PG985/8

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