



## EC Declaration of Conformity

**Manufacturers Name:** FareTec Inc.

**Manufacturers Address:** 1610 West Jackson St, Painesville, OH 44077 USA

**Manufacturer SRN:** US-MF-000014693

**Authorized Representative Name:** CMC Medical Devices & Drugs S.L.

**Authorized Representative Address:** C/ Horacio Lengo n18  
C.P 29006 Málaga-Spain

**Authorized Representative SRN:** ES-AR-000000293

**Basic UDI-DI:** ++B5418003X3

**Name of the Device:** Pelvic Binder

**Intended Use:** Pelvic Binder is a non-invasive, circumferential pelvic belt intended to stabilize pelvic fractures during transport to a definitive care facility.

**Classification:** Class I, Rule 1

**Conformity assessment route:** FareTec Inc. uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:  
  
Class I: Declaration of Conformity (Annex IV); CE Marking (Annex V); Technical Documentation (Annex II and III)

**Standards Applied:** EN 1041:2008 Information supplied by the manufacturer of medical devices  
  
EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011) EN ISO 14155:2011/AC:2011  
  
EN ISO 14971:2019 Medical devices - Application of risk management to medical devices

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EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)

This declaration of conformity is issued under the sole responsibility of FareTec Inc. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.  
All supporting documentation is retained at the premises of the manufacturer.

Signature:

CEO, FareTec

.....  
Name & Function (Signed for)

Place and date of issue:

1610 West Jackson St, # 6 Painesville, OH  
44077 USA

10/3/2022



Attachment to Declaration of Conformity for Pelvic Binder

<b>UDI-DI</b>	<b>Production Number</b>	<b>Model Description</b>
B54180030000	8003000	Pelvic Binder Military
B54180030010	8003001	Pelvic Binder Military w Traction Attachment
B54180030020	8003002	Pelvic Binder Tactical Black
B54180030030	8003003	Pelvic Binder Tactical Black w Traction attachment
B54180030040	8003004	Pelvic Binder EMS Blue
B54180030050	8003005	Pelvic Binder EMS Blue w Traction Attachment
B54180030060	8003006	Pelvic Binder EMS Red
B54180030070	8003007	Pelvic Binder EMS Red w Traction Attachment