

EC Declaration of Conformity

Manufacturers Name: FareTec Inc.

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

Manufacturer SRN:

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: ++B5411126W3

Name of the Device: Traction Splints

Intended Use: Traction Splints is a group of mechanical splinting devices intended to provide support and traction to mid-shaft femur fractures during the pre-hospital care and patient transport

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



Attachment to Declaration of conformity for Traction Splints

UDI-DI	Production Number	Model Description
B54111265120	1126512	QD-3 Leg Traction Splint, Pedi, Molded
B54111265140	1126514	QD-4 Leg Traction Splint, Adult, Molded
B54111265220	1126522	QD-3 Leg Traction Splint, Pedi, Alum
B54111265240	1126524	QD-4 Leg Traction Splint, Adult, Alum
B54111266240	1126624	CT-6 Tactical Traction Splint
B5411126624A0	1126624-A	CT-6 Military Traction Splint, Black Case, GT Cobra Buckle
B5411126624C0	1126624-C	CT-6 Military Traction Splint, Camo Case, Molded Buckle
B5411126624M0K	1126624-M	CT-6 Military Traction Splint DOD
B541112662600	1126626	CT-6 EMS Leg Traction Splint
B5411126626L0	1126626-L	CT-6 EMS Traction Splint W/Long Straps
B54111266270	1126627	CT-7 Tactical Leg Traction Splint
B541112662720	1126627-2	CT-7 Tactical Traction Splint W/2 Leg Slings
B5411126627M0	1126627-M	CT-7 Military Leg Traction Splint
B54111266280	1126628	CT-6 MidMed Traction Splint
B54111266290	1126629	CT-7 Civilian Traction Splint
B541112662920	1126629-2	CT-7 Civilian Traction Splint w/2 Leg Slings
B54111266320	1126632	CT-6 EMS Bilateral Traction Splint
B54111266360	1126636	CT-7 Traction Splint, Orange Straps, Black Case
B54111267160	1126716	QD Comb Kit, Leg Traction Splint, Molded
B54111267260	1126726	QD Comb Kit, Leg Traction Splint, Alum



risk management to medical devices

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

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Name & Function (Signed for)

Place and date of issue:

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

14 June 2021