

Declaration of Conformity Certificate

We

RCR Medical Products, LLC
POB 244
Melissa, Texas 75454
USA
844-472-7633

Declare with sole responsibility, that our product/s:

UMDNS Code	UMDNS Description	Internal Product Name	Classification Rationale per MDD
16-632	Tourniquet - strap	X8T-T	Class 1

meet, the essential requirements of Council Directive 93/42/EEC as amended by 2007/47/EEC pertaining to medical devices. Pathway of conformity per Annex VII.

Notified Body: NA

The product(s) identified above meet requirements of the Medical Devices Directive by meeting the following standards

Standard No.	Standard Description
EN 1041:2008	Information Supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device Labels, labelling and information to be supplied
EN 62366:2008	Medical Devices – Application of usability engineering to medical devices
EN ISO 13485:2016	Quality Management Systems
MEDDEV 2.7/1 rev.4	Medical Devices – Clinical Evaluation
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects
EN ISO 10993-5:2018	Medical Devices – Biological evaluation
EN ISO 14971:2012	Medical Devices – Application of risk management to medical devices

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day 15th of November 2019



NOTE: The template at hand represents the experience of mdi Europa. It does not have legal relevance. The simple usage does not automatically imply fulfillment of any regulation. For a final validation, please cross check with the applicable guidelines and regulations.

Expiry Date:

mdi Europa use only!

The necessary pre-requisites for placing the **CE** mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day 2 of December 20 19

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mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT

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