

# Declaration of Conformity Certificate

We

C-A-T Resources, LLC
483 Lakeshore Parkway
Rock Hill, SC 29730
USA
+1 803.325.9300
Manufacturer SRN: TBD
EU Rep SRN: DE-AR-000006218

Declare with sole responsibility, that our product/s:

CND/EMDN Code	Description	Internal Product Name	Risk Class per Annex VIII	Basic UDI-DI
C900103	Arterial Access Haemostasis, Percutaneous Systems	Combat Application Tourniquet (C-A-T-)	Class I – Rule 1	08603620024CR00770XQX

meet the general safety and performance requirements of Regulation (EU) 2017/745 of the European Parliament pertaining to medical devices. Pathway of conformity per Annex IV.

Intended Purpose: To occlude blood flow of an extremity in the event of life threatening hemorrhaging.


The following harmonized standards were also utilized:


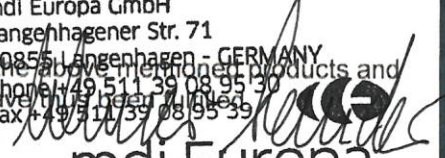

Standard	Title	Justification for Use
ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes	This is the latest International Standard Organization (ISO) standard for QMS of Medical Devices
EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices	This is the latest ISO standard for Risk Management of Medical Devices
EN ISO 15223-1:2020	Medical Devices - Symbols to be Used with Medical Device Labels, Labeling, and Information to be Supplied	This is the latest ISO standard for IFU/Label symbols
ISO 20417:2021	Information Supplied by the Manufacturer of Medical Devices	This is the latest standard for information supplied on the IFU/label
ISO 10993-1:2018	Biological Evaluation of Medical Devices	This is the latest ISO standard for biological evaluation of medical devices

**NOTE: The template at hand represents the experience of mdi Europa. It does not have legal relevance. The simple usage does not automatically imply fulfilment of any regulation.**

**For a final validation, please cross check with the applicable guidelines and regulations.**

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 11 of MDR 2017/745

Name	Function	Signature	Date	Location
Derek G Thompson	CFO		6/3/2021	Rock Hill SC USA

<p><u>mdi Europa use only!</u></p> <p>The necessary pre-requisites for placing the  mark on the above mentioned products and marketing them in all Member States of the European Union, have been checked and approved.</p> <p>Signed this day <u>16</u> of <u>June</u> 20<u>21</u></p>	<p>mdi Europa GmbH                  Langenhagener Str. 71                  30855 Langenhagen - GERMANY                  Phone +49 511 39 08 95 30                  Fax +49 511 39 08 95 39</p> <p>    <b>mdi Europa</b>                  CE-Marking Experts for Medical Devices</p>
--	--

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