# Declaration of Conformity
# Certificate

We

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|---|
| 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 |

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 |

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 been fulfilled.

Signed this day 16. of June 2021

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mdi Europa
CE-Marking Experts for 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.**