Declaration of Conformity Certificate

We

C-A-T Resources, LLC
483 Lakeshore Parkway
Rock Hill, SC 29730
USA
+1 803.325.9300
Manufacturer SRN: US-MF-000017612
EU Rep SRN: DE-AR-000006218

Declare with sole responsibility, that our product/s:

CR-007703-01-XXX	Tactical Black C-A-T Tourniquet
CR-007704-03-XXX	EMS Orange C-A-T Tourniquet
CR-007705-03-XXX	Trainer Blue C-A-T Tourniquet

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 haemorrhaging.

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
(EU) 2017/745	European Union Medical Device Regulation	This is the latest European Union Medical Device Regulation (EU MDR) 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	DerekGThomp	11/21/23	Rock Hill, SC