		Number:	REC-00188
		Revision:	2
Approvers:	Jason Herd; Amy Autovino	Effective Date:	2021-06-03
Title:	MDR Declaration of Conformity	Type:	Record

Declaration of Conformity Certificate

We

C-A-T Resources, LLC
483 Lakeshore Parkway
Rock Hill, SC 29730
USA
+1 803.325.9300

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

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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		2-15-23	Rock Hill, SC USA

18 February 2023
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 CE-Marking Experts for Medical Devices