

EG-Konformitätserklärung

EC Declaration of Conformity



DEHAS Medical Systems GmbH | Wesloer Str. 107-109 | 23568 Lübeck, Germany

**Produkt/
Medical device:**

Tourniquet - Gen.6

**Artikelnummern/
Item numbers:**

D-TOU-CAT (Ausführung in den Farben Schwarz / Blau / Orange)

**Klassifikation/
Classification:**

I

Regel 1, Anhang VIII der Medizinprodukte-Verordnung (EU) 2017/745
Rule 1, Annex VIII of Medical Device Regulation 2017/745 (MDR)

Wir erklären hiermit in alleiniger Verantwortung, dass das oben genannte Produkt mit den grundlegenden Anforderungen gemäß Anhang 1 der Medizinprodukte-Verordnung (EU) 2017/745 übereinstimmt. Alle Belegdokumente werden in den Räumlichkeiten des Herstellers aufbewahrt. Unser Qualitätsmanagement ist zertifiziert nach **EN ISO 13485:2016 + AC:2018 + A11:2021**

*We hereby declare under our sole responsibility that the above product is in conformity with the basic requirements according to Annex 1 of the Medical Device Regulation 2017/745. All supporting documents are kept on the premises of the manufacturer. Our quality management is certified according to **EN ISO 13485:2016 + AC: 2018 + A11:2021***

**Angewandte Normen/
Applied Standards:**

EN ISO 14971 : 2019
EN ISO 15223-1 : 2021
EN ISO 20417 : 2021
EN ISO 10993- 1 : 2020
EN ISO 10993- 5 : 2009
EN ISO 10993- 10 : 2013

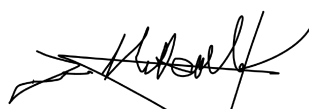
Kennzeichnung/ Marking:



Gültig bis / Valid until:

2026-11-02

Lübeck, 2024/05/21



Jens Mittendorf (Geschäftsführer /CEO)

Anhang I EG-Konformitätserklärung

Attachment I EC Declaration of Conformity

DEHAS Medical Systems – Tourniquets are tested - if applicable - to the following standards for materials:

The Material meet the Military Specification of Mil-C-32439 - A, (12.07.2017)

PU Coated w/DWR Finish and meets the nIR Spectral Reflectance ratings.

Type 1 - 1000 denier

Class 4 - 12.0 oz/sq yd, Water repellent/flame retardant

The following international Standards were tested and covered with the MIL Spec Standard

Mil-C-32439 - A

EN ISO 811:2018 - Determination of resistance to water penetration - Hydrostatic pressure test

EN ISO 12947- 2:2016 Determination of the abrasion resistance of fabrics by the Martindale method

ASTM D276 - Standard Test Methods for Identification of Fibers in Textiles

ASTM D737 -Test Method for Air Permeability of Textile Fabrics

ASTM D747 - Standard Test Method for Apparent Bending Modulus of Plastics by Means of a Cantilever Beam

ASTM D751 - Standard Test Method for Coated Fabrics

ASTM D1424 - Standard Test Method for Tearing Strength of Fabrics by Falling- Pendulum Type (Elmendorf) Apparatus

ASTM D1776/D1776M - Standard Practice for Conditioning and Testing Textiles

ASTM D1907/D1907M - Standard Test Method for Linear Density of Yarn (Yarn Number) by the Skein Method

ASTM D2582 - Standard Test Method for Puncture-Propagation Tear Resistance of Plastic Film and Thin Sheeting

ASTM D3775 - Standard Test Method for Warp (End) and Filling (Pick) Count of Woven Fabrics

ASTM D3776/03776M - Standard Test Methods for Mass per Unit Area (Weight) of Fabric

ASTM D3884- Standard Guide for Abrasion Resistance of Textile Fabrics (Rotary Platform, Double-Head Method)

ASTM D5034 - Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

ASTM D6413/D6413M - Standard Test Method for Flame Resistance of Textiles (Vertical Test)

Ende der Liste / End of list

Anhang II EG-Konformitätserklärung
Attachment II EC Declaration of Conformity

Art.-Nr./ <i>Product Code</i>	Beschreibung/ <i>Description</i>	Klasse/ <i>class</i>	IFAK P	IFAK	IFAK EMS	IFAK POL	IFAK Custom
D-TOU-CAT	First Aid Tactical Tourniquet (CAT Gen 6 Type); Mechanical	I	√	√	√	√	√

Ende der Liste / End of list