

## Declaration of Conformity Certificate

We

Tri-Tech Forensics DBA Rescue Essentials
8770 Trade St. NE
Leland, NC 28451
United States
1-719-539-4843

Declare with sole responsibility, that our product/s:

UMDNS Code	UMDNS Description	Internal Product Name	Classification Rationale per MDD
13688	Splints, Traction	STS Slishman Traction Splint	Class I, Non-Sterile, Non-Measuring, Rule 1


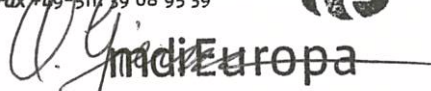
meet, the essential requirements of Council Directive 93/42/EEC as amended by 2007/47/EEC pertaining to medical devices. Pathway of conformity per Annex VII and the Essential Requirement of MDD 93/42/EEC Council Directive.

The product(s) identified above meet requirements of the Medical Devices Directive by meeting the following standards

Standard No.	Standard Description
ISO 9001:2015	Quality management systems – Requirements
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
MDD 93/42/EEC	Medical Device Directive
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN 980:2008	Symbols for use in the labelling of medical devices
(ASTM) Standard F 1980-07	American Society for Testing and Materials

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day 15 of May, 2019  \_\_\_\_\_

<u>mdi Europa use only!</u>	
The necessary pre-requisites for placing the marketing them in all Member States of the European Union have thus been fulfilled.	 <b>mdi Europa GmbH</b> Langenhagener Str. 71 • 30855 Langenhagen Phone +49-511-39 08 95 30 Fax +49-511-39 08 95 39
Signed this day <u>27</u> of <u>May</u> 20 <u>19</u>	 <b>mdi Europa</b> THE MEDICAL DEVICE SERVICE-MANAGEMENT