TRITECHFORENSICS
identify. collect. preserve

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 Eric A. Barton

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 thus been fulfilled.

Signed this day 27 of May 2019

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mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT