Declaration of Conformity

5.1 Declaration of Conformity

With regard to the Medical Device Directive 93/42/EEC and 2007/47/EC.

North American Rescue, LLC. 35 Tedwall Court, Greer SC 29650, USA declares that we are solely responsible for ensuring that the:

60-0001	Raven® 90C
60-0002	Talon® II 90C
60-0004	Stingray Litter
60-0008	IV Pole Adjustable
60-0009	Talon Assault Litter – Black
60-0010	Talon Assault Litter – Foliage
60-0011	Talon Assault Litter – Coyote
60-0014	Litter Stand
60-0022	T3TM Light Weight Assault Litter
60-0023	OSLTM
60-0024	Oversized back rest
60-0025	Talon Assault Litter – DUC
60-0027	Litter Back Rest
60-0029	Litter Stand
60-0030	Litter Carry Harness
60-0031	Mountain Litter
60-0034	Talon STANAG 2040
60-0041	Wheeled Manual Patient Transfer Device w/out Case
60-0047	Emergency Evacuation Litter
60-0048	Emergency Evacuation Litter
60-0049	Emergency Evacuation Litter
60-0050	Emergency Evacuation Litter
60-0051	Medevac Litter
60-0052	Medevac Litter
60-0061	Quick Litter
60-0070	Talon STANAG-2040/3204
60-0074W	(KIT, LITTER - K9 - BLK)
60-0063	Wheeled Litter Carrier
60-0057	RIG Series Litter Carrier
60-0082	Talon STANAG

Fulfill the essential requirements of 93/42/EEC and 2007/47/EC with the following standards applied:

ISO 14971:2012	Medical devices -- Application of risk management to medical devices
ISO 13485:2016	Medical devices – Quality management systems—Requirements for regulatory purposes

The product labeling carries CE Mark CE

The Authorized Representative is **mdi Europa GmbH,** Langenhagener Straße 71, D-30855, Langenhagen Germany.

With regard to the Directives 93/42/EEC and 2007/47/EC the conformity procedure referenced to in Article 10 and Annex VII has been followed. These devices are exempt from 89/686/EEC and 2006/42/EC.

The UMDNS Codes for these products are:

- 13818 Portable Stretchers
- 16912 Standing Frames, Mobile
- 11835 Carriers, Medical Device

The product is a Class I as defined per Rule 1 of the Medical Device Directive.

William Slevin
Director, QA/RA

Signed this 4th day of February 2020