Declaration of Conformity

With regard to the European Medical Device Regulations 2017/745.

North American Rescue, LLC
35 Tedwall Court
Greer, SC 29650 USA

declares we are solely responsible for ensuring the below devices are labelled per EN ISO 15223-1:2021, manufactured in accordance with EN ISO 13485:2016, 2017/745 Article 22 and other applicable requirements.

Device
80-0027-EU Hypothermia Prevention & Management Kit (HPMK)

Intended Use
The NAR Hypothermia Prevention & Management Kit is a first aid procedural pack pursuant to Article 22 of 2017/745.

SRN is US-PR-000007719

Device part number, variants, and UDI-DI

Part Number	Description	UDI-DI	Accessories
80-0027-EU	HPMK	00842209121366	None

Fulfills the applicable requirements of the 2017/745 Article 22 and following standards:

EN ISO 13485:2016	Medical devices – Quality management systems—Requirements for regulatory purposes
EN ISO 15223-1:2021	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 14971:2019	Risk Management for medical devices

The product labeling will not carry a CE Mark as per 2017/745 Article 22(5).

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

These devices are exempt from 89/686/EEC and 2006/42/EC.

EMDN	T030399
GMDN	58416
UMDNS	12067

This Declaration of Conformity was issued at North American Rescue, LLC, 35 Tedwall Court, Greer SC 29650, USA.

Signed this 27th day of October 2021

William Slevin
Director, QA/RA
North American Rescue, LLC