



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

North American Rescue, LLC
35 Tedwall Court
Greer, SC 29650
USA
SRN: US-MF-000007626

declares we are solely responsible for ensuring the below listed devices are labelled per EN ISO 15223-1:2021 and manufactured in accordance with EN ISO 13485:2016/A11:2021.

Devices:

30-0009	BOA Standard
30-0071	BOA XL

Intended Use

The BOA® Constricting IV Band (BOA) provides circumferential pressure on either of the upper extremities for the purpose of obtaining peripheral venous access.

Basic UDI-DI: 0842209100000000000TD038V

Device part number, variants, and UDI-DI

<i>Reference</i>	<i>Description</i>	<i>UDI-DI</i>	<i>Accessories</i>
30-0009	BOA Standard	00842209110797	None
30-0071	BOA XL	00842209110803	None

are classified per rule 1 of Annex VIII of the Medical Device Regulation (EU) 2017/745, as Class I devices in accordance with all applicable provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning medical devices.

Fulfills the general safety and performance requirements of 2017/745 with the following standards applied:



NORTH AMERICAN RESCUE®

EN ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1, 5, 10 18 and 23
EN ISO 13485:2016/A11:2021	Medical devices – Quality management systems— Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices -- Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied-General requirements

With regard to 2017/745 the conformity procedure referenced to in Annex IX has been followed. These devices are exempt from 89/686/EEC and 2006/42/EC.

The product labeling carries a CE Mark.

The Authorized Representative is mdi Europa Langenhagener Str. 71 D-30855 Hannover-Langenhagen Germany.

SRN: DE-AR-000006218

EMDN Code is C90010301

GMDN Code is 58128

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

Signed this: 20th day of July 2022

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