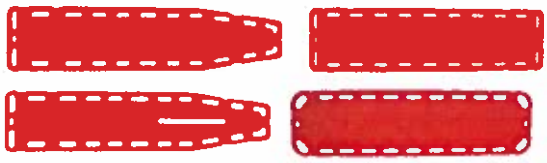
Declaration of Conformity

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Ferno-Washington, Inc.	70 Weil Way, Wilmington, OH 45177 USA	Not yet available

EU AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/Email**
Ferno S.r.l. CE	via B.Zallone, n.26,40066 Pieve di Cento, Bologna, Italy	Not yet available	+39.051.6860028 www.ferno.it

UKCA REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone**
Ferno (UK) Ltd UK CA	Ferno House Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ United Kingdom		+44 (0) 1274 851999 www.ferno.co.uk

PRODUCT IDENTIFICATION	
Product Brand Name	**Photo**
NAJO Backboards	
EMDN	
V08050103 EMERGENCY AND TRAUMATOLOGY STRETCHERS	
Intended Purpose	
A patient handling device designed to provide rigid support while transporting a patient by operators who lift and carry the stretcher.	

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
275101105	NAJO REDIHOLD 0 PINS- YELLOW	00190790002794	0190790V08050103UN
275101108	NAJO REDIHOLD 0 PINS- ORANGE	00190790002794	0190790V08050103UN
275101205	NAJO REDIHOLD 10 PINS- YELLOW	00190790002800	0190790V08050103UN
275101208	NAJO REDIHOLD 10 PINS- ORANGE	00190790002800	0190790V08050103UN
275201108	NAJO LITE 0 PINS- ORANGE	00190790002824	0190790V08050103UN
275201205	NAJO LITE 10 PINS- YELLOW	00190790002831	0190790V08050103UN
275201208	NAJO LITE 10 PINS- ORANGE	00190790002831	0190790V08050103UN

Related Accessories (if applicable):

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
n/a	n/a	n/a	n/a

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class I Self Certified Rule 1	Not applicable

Ferno-Washington, Inc. declares the above-mentioned products meet the applicable requirements of the following legislation and/or harmonized and non-harmonized standards:

- Medical Devices Regulation (EU) 2017/745
- Medical Device Directive 93/42/EEC
- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- EN 1865:1:2010+A1:2015, Part 1, Patient Handling Equipment used in Road Ambulances
- EN 597-1:2015, Furniture – Assessment of the Ignitability of Mattresses
- EN 597-2:2015 Furniture – Assessment of the Ignitability of Mattresses

COMPANY REPRESENTATIVE: Dorothy Ramsey

TITLE: VP, Global Legal & Regulatory (PRRC) **SIGNATURE:** Dorothy Ramsey

PLACE: Wilmington, OH, USA **DATE:** 06/14/2023

Document History:

Revision	Summary of Changes	Reviewer	Review Date	Effective Date
00	New Issue	D.Greene	6/14/2018	6/29/2018
00	Conversion of all historical document numbers to new database document numbers; addition of historical document number to document footer	Reiley	12/10/2018	06/29/2018
01	Updated EU Rep contact information and removed MDR references; remove page number; updated ISO to 2016	D.Greene	03/13/2019	03/13/2019
02	Updated EU Rep contact information; updated document format	D.Greene	02/18/2020	02/19/2020
03	Updated to MDR compliant format; addition of UK Rep	D.Greene	02/08/2021	03/042021
04	Update Ferno UK address and references to reg/standards	D.Greene	06/15/2021	06/16/2021
05	Addition of GMDN and EMDN fields	D.Greene	11/19/2021	11/19/2021
06	Addition of GMN and EMDN fields; general formatting	D. Greene	12/14/2021	12/15/2021