






## 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. 	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 	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
Model 71 Series Basket Stretchers	
EMDN	
V08050103	
EMERGENCY AND TRAUMATOLOGY STRETCHERS	
<b>Intended Purpose</b> An emergency patient handling device designed to transport a patient by trained, professional operators who lift and carry the stretcher.	

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0107100	71 BASKET STRETCHER, INT	00190790002596	0190790V08050103UN
0107101	71-S BASKET STRETCHER, INT	00190790002619	0190790V08050103UN
0107104	71-M BASKET-STRETCHER	00190790002565	0190790V08050103UN
0107933	71 BASKET (QTY 40)	00190790003708	0190790V08050103UN
0107972	71 BASKET STRETCHER DOMESTIC	00190790002589	0190790V08050103UN
0107973	71-S BASKET STRETCHER DOMESTIC	00190790002602	0190790V08050103UN



Related Accessories (if applicable):

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0085480	513-4 IV-POLE-FOR-71	00190790003364	0190790V0880K5
0312390	418-1 ADJ, BRIDLE W/ORG BAG	00190790003760	0190790V0880K5
0313892	430 RESTRAINT 2 PC 5' BLACK	00190790002756	0190790V0880K5
0314008	RESTRAINT, MOD 71 INTERNATIONAL	00190790004859	0190790V0880K5

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

COMPANY REPRESENTATIVE: Dorothy Ramsey

TITLE: VP, Global Legal & Regulatory (PRRC)

PLACE: Wilmington, OH, USA

SIGNATURE: Dorothy Ramsey

DATE: 01/14/2022



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	03/04/2021
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

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