



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

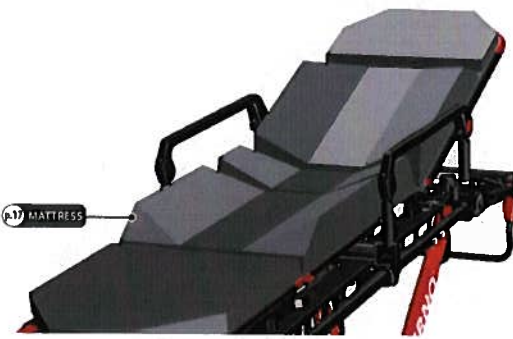
EU AUTHORIZED REPRESENTATIVE

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
Stretcher Mattresses/Pads Models 359, 360, 460 and misc EMDN V0880 MEDICAL SUPPORT EQUIPMENT - ACCESSORIES Intended Purpose Ferno mattresses/pads are used with Wheeled/Hand Carried Stretchers and are designed to provide a soft surface to the patient while being transported on the stretcher.	

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0311220	359-8 MATTRESS 28 ORG	00190790004880	0190790V0880K5
0312720	460,BOLSTER MATTRESS HS ORG	00190790003777	0190790V0880K5
0313063	460,BOLSTER MATTRESS HS BURG.	00190790003784	0190790V0880K5
0313691	360 FLAT MATTRESS HS ORANGE	00190790003814	0190790V0880K5
0313857	460-J MATTRESS BLACK	00190790004989	0190790V0880K5
0313920	MATTRESS, PROFLEXX	00190790004996	0190790V0880K5
0313997	MATTRESS, POWERFLEXX	00190790005009	0190790V0880K5



0314028	MATTRESS,PROFLEXX, POCKET	00190790005030	0190790V0880K5
0314031	MATTRESS SET, 28Z	00190790005047	0190790V0880K5
0314037	RPLCMNT HEADEND MATTRESS, 28Z	00190790005054	0190790V0880K5
0314038	RPLCMNT FOOTEND MATTRESS, 28Z	00190790005061	0190790V0880K5
0314061	MATTRESS, BLACK, JAPAN	00190790005092	0190790V0880K5
0314191	MATTRESS, 25I	00190790005115	0190790V0880K5
0314204	MATTRESS, FOOTEND PRO 28Z	00190790005139	0190790V0880K5
0314205	MATTRESS, HEADEND PRO 28Z	00190790005146	0190790V0880K5
0372250	359-20/22 MATTRESS, ORG	00190790004927	0190790V0880K5
0374857	MATTRESS, 26-S, BLACK	00190790005160	0190790V0880K5
0374904	MATTRESS, FLAT, 3-SEGMENT	00190790003906	0190790V0880K5
0374926	MATTRESS - BOLSTERED - HOOK	00190790005207	0190790V0880K5
0390120	28 ORG SEAT/BACK MATTRESS	00190790005214	0190790V0880K5
0390121	28 ORG LEG/FOOT MATTRESS	00190790005221	0190790V0880K5
0822498	KIT, MATTRESS PRO 28Z	00190790003968	0190790V0880K5
1203247	SEAT ,BACK SECTION ORG	00190790005290	0190790V0880K5
1203248	SECTION, LEG/FOOT ORG	00190790005283	0190790V0880K5
1204052	MATTRESS,HEADEND,28Z	00190790005306	0190790V0880K5
1204053	MATTRESS,FOOTEND,28Z	00190790005313	0190790V0880K5
1204060	MATTRESS, 71 BASKET	00190790005276	0190790V0880K5
1204061	MATTRESS, HEAD, 71-S BASKET	00190790005269	0190790V0880K5
1204062	MATTRESS, FOOT, 71-S BASKET	00190790005252	0190790V0880K5
1204071	MATTRESS,HEADEND,28Z BLK MDA	00190790005344	0190790V0880K5
1204072	MATTRESS,FOOTEND,28Z BLK MDA	00190790005351	0190790V0880K5
1204085	MATTRESS, HEADEND, PROZ1	00190790005320	0190790V0880K5
1204086	MATTRESS, FOOTEND, PROZ1	00190790005337	0190790V0880K5

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

COMPANY REPRESENTATIVE: Dorothy Ramsey

TITLE: VP, Global Legal & Regulatory (PRRC)

PLACE: Wilmington, OH, USA

SIGNATURE:

DATE: 02/01/2022

Dorothy Ramsey



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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