






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
Mondial® Monobloc, MB64,MB70	
EMDN	
V08050102	
SELF-LOADING STRETCHERS	
Intended Purpose	
Mondial Monobloc Wheeled Stretchers are for professional use and are intended to be used as an emergency patient handling device and can be used to transport patients in ground ambulances.	

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0054246	MONDIAL MB64 - RED - BASE PKG	00190790000806	0190790V08050102UL
0054247	MONDIAL MB64 - SLVR - BASE PKG	00190790000813	0190790V08050102UL
0054249	MONDIAL MB70 - RED - BASE PKG	00190790000837	0190790V08050102UL
0054250	MONDIAL MB70 - SLVR - BASE PKG	00190790000844	0190790V08050102UL
0054252	MONDIAL MB64 - RED - OPT1 PKG	00190790000868	0190790V08050102UL
0054253	MONDIAL MB64 - SLVR - OPT1 PKG	00190790000875	0190790V08050102UL
0054255	MONDIAL MB70 - RED - OPT1 PKG	00190790000899	0190790V08050102UL
0054256	MONDIAL MB70 - SLVR - OPT1 PKG	00190790000905	0190790V08050102UL
0054258	MONDIAL MB64 - RED - OPT2 PKG	00190790000929	0190790V08050102UL



0054259	MONDIAL MB64 - SLVR - OPT2 PKG	00190790000936	0190790V08050102UL
0054261	MONDIAL MB70 - RED - OPT2 PKG	00190790000950	0190790V08050102UL
0054262	MONDIAL MB70 - SLVR - OPT2 PKG	00190790000967	0190790V08050102UL

Related Accessories (if applicable):

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0313778	678 PEDI-MATE	00190790003562	0190790V0880K5
0313892	430 RESTRAINT 2 PC 5' BLACK	00190790002756	0190790V0880K5
0313910	430 RESTRAINT 1PC 7' BLK	00190790002763	0190790V0880K5
0313911	430 RESTRAINT 2PC 7' BLK	00190790002770	0190790V0880K5
0374874	MATTRESS - RS2/3/4 - BOLSTERED	00190790003890	0190790V0880K5
0573080	MONDIAL FL1 FASTENER	00190790005757	0190790V0880K5
0822097	PATIENT SHIELD	00190790004248	0190790V0880K5
0832024	513-EFX IV POLE	00190790003548	0190790V0880K5
1590161	PAC RAC+, POWERX1 (FWEPR+PX1)	00190790004323	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
- EN 1865-1:2010+A1:2015 Patient Handling Equipment used in Road Ambulances

COMPANY REPRESENTATIVE: Dorothy Ramsey

TITLE: VP, Global Legal & Regulatory (PRRC)

SIGNATURE:

PLACE: Wilmington, OH, USA

DATE: 01/11/2022



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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