






## Declaration of Conformity - CE

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

MANUFACTURER			
Name of Company	Address	SRN	Telephone/Email
Ferno-Washington, Inc. 	70 Weil Way, Wilmington, OH 45177-9371 U.S.A.	US-MF-000041603	+1 (937) 382-1451 fernoorders@ferno.com

EU AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/Email
Ferno S.r.l. 	Via B. Zallone n.26 40066 Pieve di Cento (BO) Italy	IT-AR-000031265	+39 (051) 6860028 www.ferno.it

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.	

REF (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
0054250	MONDIAL MB70 - SLVR - BASE PKG	00190790000844	0190790V08050102UL
0054252 (OBS: 7/13/2022)	MONDIAL MB64 - RED - OPT1 PKG	00190790000868	0190790V08050102UL
0054253	MONDIAL MB64 - SLVR - OPT1 PKG	00190790000875	0190790V08050102UL
0054256	MONDIAL MB70 - SLVR - OPT1 PKG	00190790000905	0190790V08050102UL
0054258	MONDIAL MB64 - RED - OPT2 PKG	00190790000929	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)
0374874	MATTRESS - RS2/3/4 - BOLSTERED	00190790003890	0190790V0880K5
0822097	PATIENT SHIELD	00190790004248	0190790V0880K5
1590161	PAC RAC+, POWERX1 (FWEPR+PX1)	00190790004323	0190790V0880K5

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class I, Rule 1	Not applicable

According to:

HARMONIZED AND NON-HARMONIZED STANDARDS	
Item	Description
ISO 14971:2019	Medical devices – Application of risk management to medical devices
ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
BS EN 1789:2020+A1:2023	Medical vehicles and their equipment – Road ambulances
EN 1865-1:2010+A1:2015	Patient handling equipment used in road ambulances Part 1: General stretcher systems and patient handling equipment

Complies with the essential requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.

**COMPANY REPRESENTATIVE:**

DOROTHY RAMSEY

TITLE: VP, Global Legal & Regulatory, PRRC

SIGNATURE:

PLACE: Wilmington, OH, USA

DATE: 10/23/2024

DoC Revision: 03

Record History:

Revision	Summary of Changes	Author	Effective Date
00	Initial issue on QFM-2744	D.Greene	08/15/2023
01	Initial issue on REGFM-2948-00	D.Greene	03/01/2024
02	Update of MFR SRN	D.Greene	08/01/2024
03	Update of 1789/1865 standards	D.Greene	10/23/2024