






## 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
FL1 Fastener	
EMDN	
V0880	
MEDICAL SUPPORT EQUIPMENT - ACCESSORIES	
<b>Intended Purpose</b> An accessory to a Wheeled Stretcher medical device designed to secure the compatible stretcher inside a ground-based ambulance.	

REF (Item / Catalog #)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0573080	MONDIAL FL1 FASTENER	00190790005757	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, 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
EN 1789:2020+A1:2023	Medical vehicles and their equipment – Road ambulances

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

**COMPANY REPRESENTATIVE:**

DOROTHY RAMSEY

TITLE: PRRC, VP, Global Legal & Regulatory

PLACE: Wilmington, OH, USA

DoC Revision: 02

SIGNATURE:

DATE: December 10, 2024