






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.	Submitted – pending assignment	+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
Model 71 Basket Stretchers	
EMDN	
V08050103	
EMERGENCY AND TRAUMATOLOGY STRETCHERS	
Intended Purpose	
An emergency patient handling device designed to transport a patient by trained, professional operators.	

REF (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
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)
0312390	418-1 ADJ, BRIDLE W/ORG BAG	00190790003760	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

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

SIGNATURE:

PLACE: Wilmington, OH, USA

DATE: 03/01/2024

DoC Revision: 00