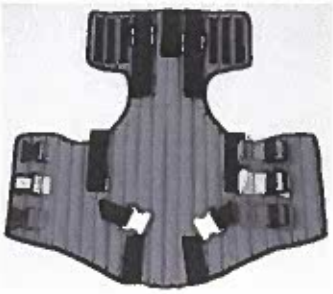
Declaration of Conformity - CE

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. CE	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 125 KED	
EMDN	
V0880 MEDICAL SUPPORT EQUIPMENT - ACESSORIES	
Intended Purpose	
The 125 KED is for professional use and is intended to be used as an emergency patient handling device for the purpose of stabilizing and immobilizing a patient during an emergency rescue and transport.	

REF (Item / Catalog #)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0313676	125 KED EX DEVICE	00190790003807	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

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: Dorothy Ramsey

PLACE: Wilmington, OH, USA

DATE: 08/01/2024

DoC Revision: 01