






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
PediMate, PediMate Plus, NeoMate	
EMDN	
V0880 MEDICAL SUPPORT EQUIPMENT – ACCESSORIES	
Intended Purpose PediMate, PediMate Plus and NeoMate restraints are for professional use and are intended to be used as an emergency patient handling device designed to secure infants and toddlers to a stretcher during transport.	

REF (Item / Catalog #)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0313778/0313778CF	678 PEDI-MATE	00190790003562	0190790V0880K5
0314115/0314115CF	PEDIMATE PLUS	00190790003593	0190790V0880K5
0314116/0314116CF	NEO MATE	00190790003555	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:

PLACE: Wilmington, OH, USA

DATE: 08/01/2024

DoC Revision: 01