






Declaration of Conformity

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

MANUFACTURER		
Name of Company	Address	SRN
Ferno-Washington, Inc.	70 Weil Way, Wilmington, OH 45177 USA	Not yet available

EU AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/Email
Ferno S.r.l. 	via B.Zallone, n.26,40066 Pieve di Cento, Bologna, Italy	Not yet available	+39.051.6860028 www.ferno.it

UKCA REPRESENTATIVE			
Name of Company	Address	SRN	Telephone
Ferno (UK) Ltd 	Ferno House Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ United Kingdom		+44 (0) 1274 851999 www.ferno.co.uk

PRODUCT IDENTIFICATION	
Product Brand Name	Photo
Pedi Mate / Neo Mate	
Intended Purpose An accessory to a Ferno Wheeled Stretcher intended to be used as a restraint to secure infants and toddlers to the stretcher	

Item / Catalog #	Item Description	Basic UDI-DI
0313778	678 PEDI-MATE	00190790003562
0314115	PEDIMATE PLUS	00190790003593
0314116	NEO MATE	00190790003555

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

Ferno-Washington, Inc. declares that the above-mentioned products meet the provision of the following legislation:

- Medical Devices Regulation (EU) 2017/745



- List other legislation/Directives as applicable:
 - Medical Device Directive 93/42/EEC
 - ISO 13485:2016

COMPANY REPRESENTATIVE: DOROTHY RAMSEY
TITLE: VP, Global Legal & Regulatory (PRRC)

SIGNATURE: Dorothy Ramsey

PLACE: Wilmington, OH, USA

DATE: 06/18/2021



Document History:

Revision	Summary of Changes	Reviewer	Review Date	Effective Date
00	New Issue	D.Greene	6/14/2018	6/29/2018
00	Conversion of all historical document numbers to new database document numbers; addition of historical document number to document footer	Relley	12/10/2018	06/29/2018
01	Updated EU Rep contact information and removed MDR references; remove page number; updated ISO to 2016	D.Greene	03/13/2019	03/13/2019
02	Updated EU Rep contact information; updated document format	D.Greene	02/18/2020	02/19/2020
03	Updated to MDR compliant format; addition of UK Rep	D.Greene	02/08/2021	03/04/2021
04	Update Ferno UK address and references to reg/standards	D.Greene	06/15/2021	06/16/2021