






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	<i>Not yet available</i>

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-MF-000031330	+39(051)6860028 www.ferno.it

UKCA REPRESENTATIVE			
Name of Company	Address	MHRA Ref Number	Telephone
Ferno (UK) Ltd 	Ferno House Stubs Beck Lane, Cleckheaton, West Yorkshire, BD19 4TZ United Kingdom	12246	+44 (0) 1274 851999 www.ferno.co.uk

PRODUCT IDENTIFICATION	
Product Brand Name	Photo
Transcend Chair Series	
EMDN	
V080502	
PATIENT TRANSFER CHAIRS	
Intended Purpose	
An emergency patient-handling device designed to assist trained operators in transporting a seated patient up or down stairs and over flat surfaces	

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0731401	TRANSCEND STAIR CHAIR BASE	00190790004040	0190790V0805024G
0731402	TRANSCEND STAIR CHAIR W/TRX	00190790004057	0190790V0805024G
0731403	TRANSCEND STAIR CHAIR W/PWRTRX	00190790004064	0190790V0805024G
0731404	TRANSCEND STAIR CHAIR EVAC	00190790004071	0190790V0805024G
0731405	TRANSCEND CHAIR W/PWRTRAX STD	00190790006334	0190790V0805024G



Related Accessories (if applicable):

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0822029	KIT INTERCONNECT CORD	00190790005566	0190790V0880K5
0822141	KIT POWER TRAX	00190790005467	0190790V0880K5
0822142	KIT U-BAR FIXED	00190790005443	0190790V0880K5
0822143	KIT U-BAR TELESCOPIC	00190790005450	0190790V0880K5
0822484	ENDURACHARGE BATTERY LI-ION	00190790005474	0190790V0880K5
0822509	KIT, WALL CHARGER	00190790005481	0190790V0880K5
0822515	KIT BATTERY ADAPT FERNO 36V US	00190790005580	0190790V0880K5
0822516	KIT BATTERY ADAPT M28 US	00190790005597	0190790V0880K5
0832198	BATTERY MILWAUKEE 28VDC	00190790005535	0190790V0880K5
0832199	CHARGER MILWAUKEE 120VAC	00190790005542	0190790V0880K5
0567086	ASSY FASTENER CHAIR	00190790006259	0190790V0880K5
0567087	ASSY FASTENER CHAIR WITH ICS	00190790006266	0190790V0880K5

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

Ferno-Washington, Inc. declares the above-mentioned products meet the applicable requirements of the following legislation and/or harmonized and non-harmonized standards:

- Medical Devices Regulation (EU) 2017/745
- Medical Device Directive 93/42/EEC
- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- EN 1865-4:2012 Patient Handling Equipment Used in Road Ambulances – Foldable Patient Transfer Chair
- ISTA 3A Packaged Products for Parcel Delivery System Shipment 70 kg (150 lb) or less
- IP5X/IPX6 Dust/Water Jet
- MIL STD 810G Method 509.5 (Salt Fog)
- IEC 60601-1-2:2014, 4th Edition, Medical Electrical Equipment
 - EN 55011:2009+A1:2010 Radiated Emissions
 - IEC 6100-1-2:2008 Electrostatic Discharge Immunity
 - IEC 61000-4-3:2010 Radiated Electromagnetic Field Immunity
 - IEC 6100-4-2:2010 Proximity Fields from RF Wireless Communications Equipment
 - IEC 61000-4-4:2012 Fast Transient/Burst Immunity
 - IEC 61000-4-6:2013 Conducted RF Immunity
 - IEC 61000-4-8:2009 Magnetic Field Immunity

COMPANY REPRESENTATIVE: Dorothy Ramsey

TITLE: VP, Global Legal & Regulatory (PRRC)

PLACE: Wilmington, OH, USA

SIGNATURE: _____

Dorothy Ramsey

DATE: 09/26/2023



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	Reiley	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 rep/standards	D. Greene	06/15/2021	06/16/2021
05	Addition of GMDN and EMDN fields	D. Greene	11/19/2021	11/19/2021
06	Addition of GMN and EMDN fields; general formatting	D. Greene	12/14/2021	12/15/2021