




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

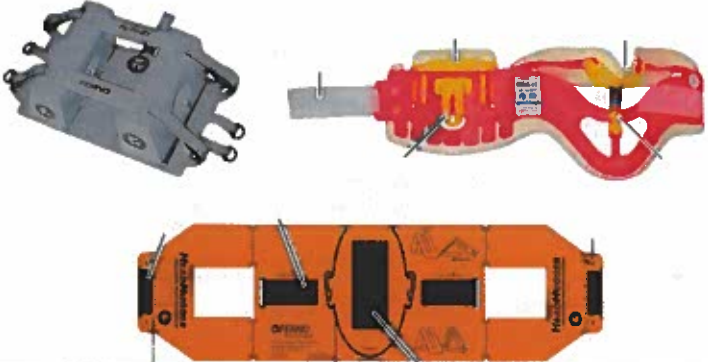
EU AUTHORIZED REPRESENTATIVE

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
Head/Cervical Immobilizers Models 445, 449, 455	
EMDN	
V0880 MEDICAL SUPPORT EQUIPMENT - ACCESSORIES	
Intended Purpose Ferno Immobilizers are for professional use and are intended to be used as an emergency patient handling device designed to aid in stabilizing and immobilizing a patient during an emergency rescue and transport to a medical facility.	

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0313855	445 HEAD IMMOBILIZER	00190790003838	0190790V0880K5
0822074	449-WIZLOC(3/PK)-TW PURCHASE #	00190790003913	0190790V0880K5
0832092	455 PLASTIC HEADHUGGER (10 PK)	00190790003975	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 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

COMPANY REPRESENTATIVE: Dorothy Ramsey

TITLE: VP, Global Legal & Regulatory (PRRC)

PLACE: Wilmington, OH, USA

SIGNATURE:

DATE: 01/14/2022



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 reg/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

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