

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 REPR	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
Model 11 Emergency Stretcher	
EMDN	
V08050103	
EMERGENCY AND TRAUMATOLOGY STRETCHERS	D. Company
Intended Purpose	
An emergency patient handling device designed to	
transport a patient by trained, professional	
operators.	And the second s

REF (Item / Catalog #)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0101100	STRETCHER,11, W/ORG-CVR	00190790002466	0190790V08050103UN
0101110	STRETCHER,11, W/MRN-CVR	00190790002459	0190790V08050103UN
0107934	11 STRETCHER W/ORG COVER'FDNY'	00190790002442	0190790V08050103UN
0153135	11-5 STRETCHER W/O COVER	00190790003753	0190790V08050103UN

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 N	ON-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

PLACE: Wilmington, OH, USA

DoC Revision: 01

GIGNATURE: Dorothy Ramsey

DATE: 08/01/2024