



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
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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
iNjX®	
EMDN	
V08050102	
SELF-LOADING STRETCHERS	
Intended Purpose	
A wheeled stretcher for professional use and intended to be used as an emergency patient handling device and can be used to transport patients in ground ambulances.	

REF (Item / Catalog #)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0015803 (OBS: 6/21/2023)	INX, FOR INLINE	00190790000004	0190790V08050102UL
0015811	INX FOR INLINE WITH DWL	00190790001339	0190790V08050102UL
0015818	INX, FOR INLINE, FOLD FORWARD	00190790006235	0190790V08050102UL
0015819	INX, FOR INLINE, SX SIDEARMS	00190790006242	0190790V08050102UL

Related Accessories (if applicable):

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0822097	PATIENT SHIELD	00190790004248	0190790V0880K5
0822451	KIT, BACKREST PANEL MNT HOOK	00190790004453	0190790V0880K5
0822452	BACKREST FRAME MNT EQUIP HOOK	00190790004460	0190790V0880K5
0822453	INX TELESCOPING FRAME STO-NET	00190790003920	0190790V0880K5
0822463	US 24V/36V CHARGER	00190790004255	0190790V0880K5
0822464	UK 24V/36V CHARGER	00190790004477	0190790V0880K5
0822465	EUROPEAN 24V/36V CHARGER	00190790004484	0190790V0880K5



0822466	AUSTRALIA 24V/36V CHARGER	00190790004491	0190790V0880K5
0822481	INX ADAPTER BRKT FOR PEDIMATE	00190790004507	0190790V0880K5
FWEPRI	PAC RAC, INTRAXX - INX/MONDIAL	00190790004446	0190790V0880K5
FWESX	SURFACE EXTENDER PAIR	00190790004422	0190790V0880K5
FWESLH	SLH, SIDE LIFT HANDLE PAIR	00190790004439	0190790V0880K5
000LBSJRINX	LBS JR, INX	00190790006181	0190790V0880K5

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:

Dorothy Ramsey

PLACE: Wilmington, OH, USA

DATE: 08/01/2024

DoC Revision: 01