



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
Mondial® Transporter, ST64, ST70	
EMDN	
V08050102	
SELF-LOADING STRETCHERS	
Intended Purpose	
Mondial Transporter Wheeled Stretchers are for professional use and are intended to be used as an emergency patient handling device and can be used to transport patients in ground ambulances. The patient surface may be detached and used as a Hand Carried Stretcher as well.	

REF (Item / Catalog #)	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0054219	MONDIAL ST70 - RED - BASE PKG	00190790000646	0190790V08050102UL
0054222	MONDIAL ST64 - RED - BASE PKG	00190790001247	0190790V08050102UL
0054227	MONDIAL ST64 - SLVR - BASE PKG	00190790000660	0190790V08050102UL
0054228	MONDIAL ST70 - SLVR - BASE PKG	00190790000677	0190790V08050102UL
0054231	MONDIAL ST70 - RED - OPT1 PKG	00190790000707	0190790V08050102UL
0054232	MONDIAL ST70 - SLVR - OPT1 PKG	00190790000714	0190790V08050102UL
0054238	MONDIAL ST64 - RED - OPT2 PKG	00190790000745	0190790V08050102UL
0054239	MONDIAL ST64 - SLVR - OPT2 PKG	00190790000752	0190790V08050102UL
0054241	MONDIAL ST70 - RED - OPT2 PKG	00190790000776	0190790V08050102UL
0054274	MONDIAL ST70-RED-TUBE SLD-OP2	00190790001049	0190790V08050102UL



Related Accessories (if applicable):

Item / Catalog #	Item Description	GTIN (UDI-DI)	GMN (Basic UDI-DI)
0153233	RS 2-2	00190790001469	0190790V08050103UN
0153234	RS 2-3	00190790001476	0190790V08050103UN
0153240	RS 2-1 W/O STORAGE TRAY	00190790001513	0190790V08050103UN
0374874	MATTRESS - RS2/3/4 - BOLSTERED	00190790003890	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
BS EN 1789:2020+A1:2023	Medical vehicles and their equipment – Road ambulances
EN 1865-1:2010+A1:2015	Patient handling equipment used in road ambulances Part 1: General stretcher systems and patient handling equipment

Complies with the essential requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.

COMPANY REPRESENTATIVE:

DOROTHY RAMSEY

TITLE: VP, Global Legal & Regulatory, PRRC

SIGNATURE:

Dorothy Ramsey

PLACE: Wilmington, OH, USA

DATE: 02 December 2024

DoC Revision: 02