



## 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.<br> | 70 Weil Way, Wilmington, OH 45177-9371 U.S.A. | Submitted – pending assignment | +1 (937) 382-1451<br>fernoorders@ferno.com |

| EU AUTHORIZED REPRESENTATIVE                                                                       |                                                           |                 |                                   |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------|-----------------|-----------------------------------|
| Name of Company                                                                                    | Address                                                   | SRN             | Telephone/Email                   |
| Ferno S.r.l.<br> | Via B. Zallone n.26<br>40066 Pieve di Cento (BO)<br>Italy | IT-AR-000031265 | +39 (051) 6860028<br>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) |
|------------------|--------------------------------|----------------|--------------------|
| 0153232          | RS 2-1                         | 00190790001452 | 0190790V08050103UN |
| 0153233          | RS 2-2                         | 00190790001469 | 0190790V08050103UN |
| 0153234          | RS 2-3                         | 00190790001476 | 0190790V08050103UN |
| 0153240          | RS 2-1 W/O STORAGE TRAY        | 00190790001513 | 0190790V08050103UN |
| 0153247          | RS 2-2 FDS                     | 00190790001544 | 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                                     |
| EN 1865-1:2010+A1:2015         | Patient Handling Equipment used in Road Ambulances                                                                      |
| EN 1789:2020, Part 5.3 and 4.4 | Medical Vehicles and their Equipment – Road Ambulances                                                                  |

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:

PLACE: Wilmington, OH, USA

DATE: 03/01/2024

DoC Revision: 00