

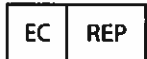


DECLARATION OF CONFORMITY (DOC)

Manufacturer/EU Representative:



Ferno-Washington, Inc.
70 Well Way
Wilmington, Ohio 45177-9371 U.S.A.
1.937.382.1451



FERNO S.r.l.
via B. Zallone, n. 26, 40066
Pieve di Cento, Bologna, Italy
+39.051.6860028

Trade Name: FERNO® - MONDIAL® RS Stretchers

SRN: N/A

Item/Catalogue #	Item Description	UDI-DI Number (GTIN)	Risk Class
0153232	RS 2-1	00190790001452	Class I
0153233	RS 2-2	00190790001469	Class I
0153234	RS 2-3	00190790001476	Class I
0153235	RS 3-1	00190790001483	Class I
0153236	RS 3-2	00190790001490	Class I
0153237	RS 4-2	00190790001506	Class I
0153240	RS 2-1 W/O STORAGE TRAY	00190790001513	Class I
0153247	RS 2-2 FDS	00190790001544	Class I

Intended Use of Medical Device: a device consisting of a lightweight frame, or of two poles with a cloth or metal platform on which a patient can be carried

Conformity Assessment: Class I medical device; self-certification by manufacturer; no requirement for NB

In accordance with Council Directive 93/42/EEC (MDD), Ferno-Washington, Inc. ("Ferno") declares the above named product(s) comply with the applicable provisions of the Medical Device Directive (MDD).

Ferno maintains an ISO 13485:2016 certification for its Quality Management System ensuring all medical devices are manufactured and distributed using consistent quality standards and post market surveillance and vigilance is maintained.

Compliance to additional standards/directives is noted as applicable:

EN 1865-1:2010+A1:2015


EN 1789:2007+A2:2014

This Declaration of Conformity is issued on this 19th day of February, 2020 in Wilmington, Ohio, USA, under the sole responsibility of the manufacturer.

FERNO-WASHINGTON, INC.

By: Dorothy Ramsey


Title: VP, Global Legal & Regulatory


Signature



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EC	REP
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Pieve di Cento, Bologna, Italy
+39.051.6860028

Trade Name: FERNO® - MONDIAL® TRANSPORTER

SRN: N/A

Item/Catalogue #	Item Description	UDI-DI Number (GTIN)	Risk Class
0054219	MONDIAL ST70 - RED - BASE PKG	00190790000646	Class I
0054220	MONDIAL ST70 - GRN - BASE PKG	00190790001254	Class I
0054222	MONDIAL ST64 - RED - BASE PKG	00190790001247	Class I
0054223	MONDIAL ST64 - GRN - BASE PKG	00190790000653	Class I
0054227	MONDIAL ST64 - SLVR - BASE PKG	00190790000660	Class I
0054228	MONDIAL ST70 - SLVR - BASE PKG	00190790000677	Class I
0054229	MONDIAL ST64 - RED - OPT1 PKG	00190790000684	Class I
0054230	MONDIAL ST64 - SLVR - OPT1 PKG	00190790000691	Class I
0054231	MONDIAL ST70 - RED - OPT1 PKG	00190790000707	Class I
0054232	MONDIAL ST70 - SLVR - OPT1 PKG	00190790000714	Class I
0054238	MONDIAL ST64 - RED - OPT2 PKG	00190790000745	Class I
0054239	MONDIAL ST64 - SLVR - OPT2 PKG	00190790000752	Class I
0054240	MONDIAL ST64 - GRN - OPT2 PKG	00190790000769	Class I
0054241	MONDIAL ST70 - RED - OPT2 PKG	00190790000776	Class I
0054242	MONDIAL ST70 - SLVR - OPT2 PKG	00190790000783	Class I
0054243	MONDIAL ST70 - GRN - OPT2 PKG	00190790000790	Class I
0054274	MONDIAL ST70-RED-TUBE SLD-OP2	00190790001049	Class I

Intended Use of Medical Device: a device consisting of a platform mounted on a wheeled frame that is designed to transport patients in a horizontal position and may be used in an ambulance

Conformity Assessment: Class I medical device; self-certification by manufacturer; no requirement for NB

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