



DECLARATION OF CONFORMITY (DOC)

Manufacturer/EU Representative:



Ferno-Washington, Inc.
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Wilmington, Ohio 45177-9371 U.S.A.
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FERNO S.r.l.
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Trade Name: FERNO® - MONDIAL® MONOBLOC

SRN: N/A

Item/Catalogue #	Item Description	UDI-DI Number (GTIN)	Risk Class
0054246	MONDIAL MB64 - RED - BASE PKG	00190790000806	Class I
0054247	MONDIAL MB64 - SLVR - BASE PKG	00190790000813	Class I
0054248	MONDIAL MB64 - GRN - BASE PKG	00190790000820	Class I
0054249	MONDIAL MB70 - RED - BASE PKG	00190790000837	Class I
0054250	MONDIAL MB70 - SLVR - BASE PKG	00190790000844	Class I
0054251	MONDIAL MB70 - GRN - BASE PKG	00190790000851	Class I
0054252	MONDIAL MB64 - RED - OPT1 PKG	00190790000868	Class I
0054253	MONDIAL MB64 - SLVR - OPT1 PKG	00190790000875	Class I
0054255	MONDIAL MB70 - RED - OPT1 PKG	00190790000899	Class I
0054256	MONDIAL MB70 - SLVR - OPT1 PKG	00190790000905	Class I
0054258	MONDIAL MB64 - RED - OPT2 PKG	00190790000929	Class I
0054259	MONDIAL MB64 - SLVR - OPT2 PKG	00190790000936	Class I
0054260	MONDIAL MB64 - GRN - OPT2 PKG	00190790000943	Class I
0054261	MONDIAL MB70 - RED - OPT2 PKG	00190790000950	Class I
0054262	MONDIAL MB70 - SLVR - OPT2 PKG	00190790000967	Class I
0054263	MONDIAL MB70 - GRN - OPT2 PKG	00190790000974	Class I
0054264	MONDIAL MB64 - RED - OPT3 PKG	00190790000981	Class I
0054267	MONDIAL MB70 - RED - OPT3 PKG	00190790001018	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

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