DECLARATION OF CONFORMITY (DOC)

Manufacturer/EU Representative:

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

EC REP
FERNO S.r.l.
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+39.051.6860028

Trade Name: FERNO®

SRN: N/A

Item/Catalogue #	Item Description	UDI-DI Number (GTIN)	Risk Class
0107100	71 BASKET STRETCHER, INT	Not implemented to date	I
0107101	71-S BASKET STRETCHER, INT	Not implemented to date	I
0107933	71 BASKET (QTY 40)	Not implemented to date	I
0107972	71 BASKET STRETCHER, DOM	Not implemented to date	I
0107973	71-S BASKET STRETCHER, COM	Not implemented to date	I
0108013	71 BASKET INT FR	Not implemented to date	I
0107104	71-M BASKET-STRETCHER	Not implemented to date	I

Intended Use of Medical Device: a hand-carried stretcher consisting of a lightweight frame 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:

This Declaration of Conformity is issued on this 12th day of October, 2020 in Wilmington, Ohio, USA, under the sole responsibility of the manufacturer.

FERNO-WASHINGTON, INC.

By: Dorothy Ramsey

Title: VP, Global Legal & Regulatory

Dorothy Ramsey

Signature: