FERNO

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.
via B. Zallone, n. 26, 40066
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+39.051.6860028

Trade Name: FERNO®

SRN: N/A

Item/Catalogue #	Item Description	UDI-DI Number (GTIN)	Risk Class
0313923	677 MEDKIDS PEDI-SLEEVE	N/A – pending implementation	EU – Class I FDA – Class I

Intended Use of Medical Device: A device intended to immobilize a limb or an extremity.

Conformity Assessment: EU – Class I, self-certification;
FDA – Listing #D147616, Product Code: NOC, Non-inflatable extremity splint

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 10th day of June, 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