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
Pieve di Cento, Bologna, Italy
+39.051.6860028

Trade Name: FERNO®

SRN: N/A

| Item/Catalogue # | Item Description | UDI-DI Number (GTIN) | Risk Class |
|---|---|---|---|
| 0313855 | 445 HEAD IMMOBILIZER | Not implemented to date | I |

Intended Use of Medical Device: a non-inflatable extremity splint intended to immobilize limbs or extremity

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 1st day of July, 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:**