DECLARATION OF CONFORMITY (DOC)

Manufacturer:

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

Authorized EU Representative:

EC REP
Ferno Washington Italia S.r.l.
via B. Zallone, n. 26, 40066
Pieve di Cento, Bologna, Italy
+39.051.6860028

Name of Medical Device:	Model 678 Pedi-Mate
Risk Class of Medical Device:	FDA Class I
	MDD Class I
Item and/or Catalogue Number:	0313778
UDI-DI of Medical Device, if applicable:	N/A
Intended Use of Medical Device:	Pre-Hospital Infant Immobilization
Conformity Assessment:	N/A (Class 1, self-certification)

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 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.

This Declaration of Conformity is issued on this 23 day of April, 2019 in Wilmington, Ohio, USA.

FERNO-WASHINGTON, INC.

By: Dorothy Ramsey

Title: Vice President Legal and Regulatory Compliance

Dorothy Ramsey

Signature