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2016

DECLARATION OF CONFORMITY

Manufacturer: Ferno-Washington, Inc.

Manufacturer's Address: 70 Weil Way
Wilmington, Ohio
USA

Name of Device(s): iNfX Integrated Patient Transport & Loading System

Class of Device(s): I

Intended Use: Patient Transport

In accordance with European Community Council Directive 93/42/EEC, Annex VII, Ferno-Washington Inc. declares the products that bear the CE mark conform with all the provisions of this Directive that apply to them and also conform to the essential requirements of the applicable provisions listed in EN 1789:2007.

Ferno-Washington Inc. products have been determined to be a Class I device according to Article 9.1 and using classification criteria from Annex IX of the Directive.

Ferno-Washington Inc. or representative will make available upon request all applicable technical documentation to allow assessment of conformity of its products in accordance with Annex VII, Sections 2 and 3.

Ferno-Washington Inc. has a systematic procedure in place to review experience gained from its devices in the post-production phase, taken appropriate corrective action based on this experience and report malfunctions to the competent authorities in accordance with Annex VII, Section 4.

Shawn Fitzgerald
Director of Quality