

Declaration of Conformity

Regulation (EU) 2017/745

Manufacturer: Ferno Canada Inc.
Manufacturer Address: 2460 Tedlo Street, Mississauga, Ontario, L5A 3V3, Canada
EU Representative: FERNO S.r.l., Via B. Zallone n.26 – 40066 Pieve di Cento (BO) - Italy
Unique registration number: *(available when the managing system will be implemented by the European Commission)*
(Art.31 (2))

The manufacturer declares under its own responsibility that the medical device (s):

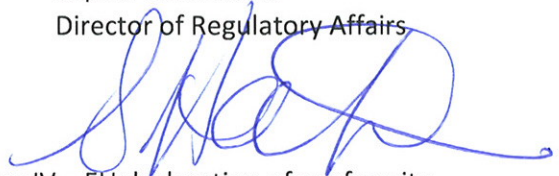
Name of device(s): NeoMate Infant Restraint System
Class of device(s): I
(Annex VIII)
Annex applied for the CE marking: Annex II and Annex III
Intended use: Immobilization
Base UDI-DI: *(available when the managing system will be implemented by the European Commission)*
(Art. 29 (1))

**complies with the essential requirements listed in Annex I of the European regulation
2017/745 concerning Medical Devices**

Ferno Canada Inc. is a Health Canada registered company (Establishment #1447)

Dated April 15, 2020

Sophia Hatsisavvas
Director of Regulatory Affairs



This document is compiled in accordance with Annex IV – EU declaration of conformity