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: *(Art.31 (2))*	(*available when the managing system will be implemented by the European Commission)*

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

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

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