Declaration of Conformity

for Manual Wheelchairs

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Manual Wheelchairs
Legal Manufacturer: (Name on Label)	**Motion Composites** 160 Armand-Majeau Sud, Saint-Roch-de-l'Achigan (QC), J0K 3H0, Canada
SRN:	N/A (Not yet available)
Basic UDI-DI:	81177400MCMANUALWC2020FH
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Wheelchair is a manually operated device intended to be used as a means of mobility for persons restricted to a sitting position.
MDR Classification:	Class I [Rule 1]
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Self-declaration, issuing of the EU declaration of conformity in Article 19 and drawing up of the technical documentation set out in Annexes II and III of the EU MDR 2017/745.

Name Bertrand Plourde **Position** Quality Director

Signed  **Date** 20-04-2021 **Place** Motion Composites

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

2020-09-16

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
ISO 7176 Series	Wheelchairs

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	GMDN Code
APEX A	APEX Aluminium	41620
APEX C	APEX Carbon	41620
Helio A6	Helio A6	41622
Helio A7	Helio A7	41622
Helio C2	Helio C2	41622
Helio Kids	Helio Kids	41622
MOVE	MOVE	41622
VELOCE	VELOCE	41622

Version History

Version	Compiled by	Date	Description
2.0	Catherine Marquis	20 april 2021	Second issue under MDR 2017/745
1.0	Kenneth Shaw	21 May 2020	First issue under MDR 2017/745.