

Declaration of Conformity

for Wheelchair Backs, Cushions and Accessories

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

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

General Product Name:	Wheelchair Backs, Cushions and Accessories
Legal Manufacturer: (Name on Label)	Dynamic Health Care Solutions (1422791 Ontario Ltd), 753011 Second Line EHS Orangeville, ON, L9W 5W4 Canada
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Assistive medical device for wheelchair support: back, cushions and accessories.
MD Directive Classification:	Class I
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name TONY PERSANO Position DIRECTOR PROD. DEV. SCATING
Signed [Signature] Date 01/10/2021

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.

Appendix I – Applicable Standards

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

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
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

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
	XTEND	45887
	XTEND DEEP	45887
	XTEND LOW	45887
	XTEND LOW DEEP	45887
	XTEND KIDS	45887
	CLASSIC	45887
	CLASSIC DEEP	45887
	UFIT	45887
	UFIT DEEP	45887
	UFIT II	45887
	UFIT II DEEP	45887
	OPTIMA	45887
	OPTIMA DEEP	45887
	OPTIMA CARBON	45887
	OPTIMA CARBON DEEP	45887
	ARMADILLO	45887
	ARMADILLO WITH VICAIR CUSHION	45887
	VC BACK SUPPORT	45887
	Nxt LATERAL SUPPORTS	36254
	Nxt MULTI FIT HEAD SUPPORTS	36254
	BIOFIT CUSHION	11100
	NUFIT CUSHION	11100

Version History

Version	Compiled by	Date	Description
1.0	Tony Persaud	01/10/2021	First issue