

Declaration of Conformity – DoC

- *V-Trak Backrest range Including hardware and accessories.*

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 Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	V-Trak Backrest range Including hardware and accessories
Legal Manufacturer: (Name on Label)	V-Trak ltd 17 Kent Rd Bridgend industrial estateWales United Kingdom CF31 3TU
Basic UDI-DI:	506004839VT0001ZU
Manufacturers SRN:	TBC
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Wheelchair backrest system
MDR Classification:	Class I
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Assessment Route	Self-certification

Name Russell Penman **Position** Director

Signed



Date 27/04/2021

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.

EU Declaration of Conformity

Appendix I – Applicable Standards

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

Standard/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 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
ISO 16840 - 4	Crash testing - means of assessing frontal impact crashworthiness of seating systems without the host wheelchair by using a surrogate wheelchair base.
ISO 7176-16 / EN 1021	Furniture. Assessment of the ignitability of upholstered furniture. Ignition source smouldering cigarette

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
AX-----	BACKRESTS	36254
HP/HS-----	HEADRESTS	41119
CM / VL -----	HARDWARE	37744
TS-----	LATERALS	32988

Version History

Version	Compiled by	Date	Description
1.0	R Palmer	2015	First issue
2.0	R. Penman	2021	Eu Representative addition
3.0	R. Penman	27/04/21	MDR changes and additions