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## Declaration of Conformity

### for the P POD BEAN SEAT

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:	P POD Bean seat
Legal Manufacturer: (Name on Label)	<u>Specialised Orthotic Services Ltd</u> Units 127-128 Fauld Industrial Park, Tutbury, Nr. Burton-upon-Trent, Staffordshire, DE13 9HS
Manufacturers SRN:	Not Yet Available
Basic UDI-DI:	50561260PPOD4100KB
Variants:	As per Appendix II (This document) — Product Listing/Schedule
Intended Purpose:	To help provide postural correction and comfort for those with a disability requiring support due to injury or handicap.
MDR Risk Classification:	Medical device class I as defined by rule 1 of Annex VIII of EU 2017/745.
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name: Position:

Signed Date  
 Specialised Orthotic Services Ltd

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 (CS):

Standard/CS/Document Name	Description
EN ISO 13485:2016	Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes
EN ISO 14971:2012 / ISO 14971:2019	Medical Devices — Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 9001-2015	Quality Management system

**Appendix II — Product Listing/Schedule**

Catalogue Number	Device Name	GMDN Code
SOS40037	P Pod Bean Seat Full Kit - Micro	44361
SOS10040	P Pod Bean Seat Full Kit – Size 1	44361
SOS10046	P Pod Bean Seat Full Kit – Size 2	44361
SOS10062	P Pod Bean Seat Full Kit – Size 2.5	44361
SOS10041	P Pod Bean Seat Full Kit – Size 3	44361
SOS10063	P Pod Bean Seat Full Kit – Size 3.5	44361
SOS10047	P Pod Bean Seat Full Kit – Size 4	44361
SOS10064	P Pod Bean Seat Full Kit – Size 4.5	44361
SOS10042	P Pod Bean Seat Full Kit – Size 5	44361
SOS10065	P Pod Bean Seat Full Kit – Size 5.5	44361
SOS10048	P Pod Bean Seat Full Kit – Size 6	44361
SOS10049	P Pod Bean Seat Full Kit - Size 6.5	44361
SOS10044	P Pod Bean Seat Full Kit – Custom – Small/Medium	44361
SOS10045	P Pod Bean Seat Full Kit – Custom – Large	44361
SOS10030	P Pod Bean Seat Full Kit – Custom – Extra Large	44361

Note: Each catalogue number listed in Appendix II can be followed by a colour (CC) and if temperature regulating material has been selected (/O) (e.g. SOS10040DR/O, where 'DR corresponds to 'Dark Red' and '/O' indicates has been included). The list of possible colours is given below.

Colour Code	Colour Name
DRX	RED DARTEX
NBDX	NAVY BLUE DARTEX
BDX	BLACK DARTEX
DR	DARK RED
CP	CERISE PINK
MP	MERMAID PINK
PB	POOL BLUE
SG	SEAHORSE GREEN
WB	WHALE BLUE
JP	JELLYFISH PURPLE
NB	NAVY BLUE
DG	DARK GREEN
BL	BLACK
SR	STARFISH RED

### Version History

Version	Compiled by	Date	Description
ORIGINAL	M Perks	01/08/2014	P Pod bean seat
2			
3	DC / SP / Stephen Howe	27/01/2022	Addition of colour codes, updated applicable standards