CE

EC Declaration of Conformity

Manufacturers Name:	SPEX Limited
Manufacturers Address:	32 Detroit Drive, Rolleston 7675, New Zealand
SRN (Single Registration Number):	NZ-MF-000009327
Authorized Representative Name:	BEO MedConsulting Berlin GmbH
Authorized Representative Address:	Helmholtzstraße 2–9, Aufgang A D-10587 Berlin, Germany
Name of the Device, Basic UDI-DI:	Spex Wheelchair seating system consisting of:

Cushion	94200517CUSHIONPP	Spex Vigour Cushion, Spex Classic Cushion, Spex Flex Cushion, Spex Constructa Shape Cushion, Spex Constructa Flex Cushion, Spex Wonderseat Seating System, Spex Universal Positioning Base, Spex Hip Flexion Contour Universal Positioning Base, Spex Ischial Contour Universal Positioning Base,
Back Support	94200517BACKSUPPORTFL	Spex Vigour Back Support, Spex Manta Back Support, Spex Classic Back Support, Spex Classic 'T' Shape Back Support, Spex SuperShape Back Support, Spex XLella Bariatric Back Support, Spex Tessellated Positioning Kit, Spex Zygo Back Support, Spex Adapta Back Supports, Spex Conmfi Back Support, Spex Growth-Adjust Back Support, Spex Back Support Hardware, Power Recline Adapter Mount, Standing Powerchair Adapter Mount
Lateral Trunk Support	94200517LATERALTRUNKRU	Paediatric Swing Away Lateral Trunk Support Hardware, Lateral Trunk Support Hardware, Lateral Trunk Support Pad
Seat Base	94200517SEATBASETQ	Spex Seat Base Hardware, Seat Base Accessories
Medial Thigh Support	94200517MEDTHIGHSZ	Wonderseat Medial Thigh Support, Medial Thigh Support Pad,
Head Support	94200517HEADRESTLR	Head Support Hardware, Stylo 160 Head Support Hardware, Stylo 260 Head Support Hardware, Stylo 130 Head Support Hardware, Wonderseat Head Support Hardware, Head Support Pad
Lateral Thigh Support	94200517LATERALTHIGHLX	Spex Lateral Thigh Support Hardware, Spex Lateral Thigh Support Pads, Wonderseat Lateral Thigh Support Pad
Arm Support	94200517ARMU9	Spex Lateral Thigh Support Hardware, Spex Lateral Thigh Support Pads, Wonderseat Lateral Thigh Support Pad

Anterior Trunk Positioning	94200517ANTERIORTRUNK48	Shoulder Strap Guides/ Retainers, H-Harness, Retractor Harness, Vest Harness, Centre-Point Harness, Chest Strap, Wonderseat Padded Centre-Point Shoulder Harness
Anterior Pelvic Positioning	94200517ANTERIORPELVIC9M	2 Point Padded Hip Belt, 2 Point Padded Centre-Pull Hip Belt, 4 Point Padded Side- Pull Hip Belt, 4 Point Padded Centre-Pull Hip Belt, 4 Point Padded Dual Centre-Pull Hip Belt, Wonderseat 4-Point Padded Hip Belt
Limb Stabilisers	94200517LIMBSTABILISERVW	Foot Fasts, Calf Straps, Calf Panel, Heel Loops, Forearm Straps, Foot Plate Padding
Tray Table	94200517TRAYQQ	Wonderseat Tray Table
Spex Wonderseat	94200517WONDERSEATDT	Wonder Seat Space, Wonderseat Bounce
Spex for Bingo	94200517SPEXFORBINGO9Q	Spex for Bingo Cushion, Spex for Bingo Back Support, Spex for Bingo Head Support, Spex for Bingo Arm Support, Spex for Bingo Axial Pelvic Support, Spex for Bingo Axial Swing-Away Lateral Support, Spex for Bingo Foot Place Spacer Block, Spex Padded centre-point harness, Spex 4-point padded Hip Belt
Intended Purpose:		Spex Seating products are intended for users (disabled and/or discomforted) that require specific postural and positioning support to provide comfort for body function in a sitting posture on wheelchairs for daily activities and for transportation in vehicles. It is designed with ergonomic adjustments to provide improved personal body-posture conditions and/or to help prevent/reduce physical problems associated with sedentary work or activities
Classification:		Class 1: EC conformity declaration according to Annex VIII, rule 1
Conformity assessment route:		Spex Ltd uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745: Conformity assessment procedure: MDR Art. 52 & Annex II, III (Class I)

This declaration of conformity is issued under the sole responsibility of Spex Ltd. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.
This declaration is supported by the following Quality Management System certification:

- ISO 13485:2016 Certificate Number: 3231 issued May 2023 by Telarc
- Spex Limited uses the following procedures for the CE labelling oof their products according to the Regulation MDR 2017/745: Conformity Assessment Procedure: Article 52, Annex II and III (Class I)

This Declaration is valid for all products concerned bearing the CE mark and manufactured by the above entitled "Manufacturer".
All supporting documentation is retained at the premises of the manufacturer.

Signature:

K Chapman.....
Kimberley Chapman
Business Performance Manager
Spex Limited

Place and date of issue:
Rolleston, New Zealand
12 December 2024

spex
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