CE

EC Declaration of Conformity

Manufacturers Name:	SPEX LTD
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:	Helmholtzstr. 2-9, D-10587 Berlin, Germany
Name of the Device, Basic UDI-DI:	Spex Wheelchair seating system consisting of:

Cushion	94200517CUSHIONPP
Back Support	94200517BACKSUPPORTFL
Lateral Trunk Support	94200517LATERALTRUNKRU
Seat Base	94200517SEATBASETQ
Medial Thigh Support	94200517MEDTHIGHSZ
Head Support	94200517HEADRESTLR
Lateral Thigh Support	94200517LATERALTHIGHLX
Arm Support	94200517ARMU9
Anterior Trunk Positioning	94200517ANTERIORTRUNK48
Anterior Pelvic Positioning	94200517ANTERIORPELVIC9M
Limb Stabilisers	94200517LIMBSTABILISERVW
Spex for BINGO	94200517SPEXFORBINGO9Q

Product name:	Vigour Cushion, Spex Classic Standard Contour Cushion, High Contour Cushion, Super High Contour Cushion, Flex Cushion, Vigour Back Support, Manta Back Support, Comfi Back Support, Spex Classic Back Support, SuperShape Back Support, XLella Back Support, Zygo Back Support, Adapta Back Support, Lateral Trunk Support, Seat Base, Medial Thigh Support, Circle Head Support, Adjustable Lateral Head Support, Comfort Head Support, Extended Lateral Head Support, Standard Lateral Head Support, Contour Head Support, Stylo 160, Stylo 260, Stylo 130, Lateral Thigh Support, Arm Support, H Harness, Retractor Harness, Vest Harness, Centre Point Harness, Chest Strap, Hip Belt, Foot

Fasts, Calf Straps, Calf Panels, Heel Loops, Forearm Straps, Spex for BINGO

Intended Purpose: Spex Seating is 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.

Classification: Class 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)

Class 1: EC conformity declaration according to Annex VIII, rule 1

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.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and date of issue:

Rolleston, New Zealand
21 April 2022

KChapman.....
Kim Chapman
Business Performance Manager
Spex Ltd