CE

EC DECLARATION OF CONFORMITY

Manufacturer Name:	POD Active Pty Ltd		
Manufacturer Address:	Level 3, 115 Myers Street, Geelong, Victoria 3220 AUSTRALIA		
Authorised Representative Name:	Wellkang Ltd.		
Authorised Representative Address:	Ireland (EU27) Office (Dublin Office): The Black Church, St. Mary's Place Dublin 7, D07 P4AX Ireland		
SRN (Single Registration Number):	*AU-MF-000003989*		
Basic UDI-DI:	*Pending*		
Name of the Device(s):	POD K4 2.0 Knee Brace POD K8 2.0 Knee Brace CTi MISSION BRACE		
Product Codes:	**POD K4 2.0 Knee Brace:**	**POD K8 2.0 Knee Brace:**	**CTi MISSION BRACE:**
	POD K4 2.0 KNEE BRACE	POD K8 2.0 KNEE BRACE	CTI-3001 CT1-2001 CTI-3002 CTI-2002 CTI-3003 CTI-2003 CTI-3004 CTI-2004 CTI-3005 CTI-2005 CTI-3001-PL CTI-2001-PL CTI-3002-PL CTI-2002-PL CTI-3003-PL CTI-2003-PL CTI-3004-PL CTI-2004-PL CTI-3005-PL CTI-2005-PL
Intended Purpose:	The device provides additional support to knee joints and may function in the following modes: • Prophylactic where it is intended to prevent and/or reduce the severity of injuries to the knee (typically prior to injury); • Functional where it is intended to provide support and stability to previously injured knees and sometimes following surgery;		

	• Rehabilitative where it is intended to provide support and stability and limit potentially harmful or injurious knee movement to the knee joint following recent injury or surgery.
Classification:	Class 1 (non-sterile; no measuring function).
Conformity Assessment Route:	POD Active Pty Ltd uses the following procedure for the CE labelling of their products according to the Regulation MDR 2017 / 745: Class 1: EC conformity declaration according to Annex VIII.
Validity:	This declaration of conformity is valid for one (1) year from the date of issue or when the technical documentation is revised.

This declaration of conformity is issued under the sole responsibility of POD Active Pty Ltd.

We hereby declare that the medical devices specified above meet the provisions of the Regulation (EU) MDR 2017 / 745 for medical devices.

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

Declared on Friday, 9 July 2021 by:

Signature:

Geoff Maloney
Director, POD Active Pty Ltd

Place and date of issue (DD.MM.YYYY):
Level 3, 115 Myers Street
Geelong, Victoria 3220
AUSTRALIA

Friday, 9 July 2021