EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

***Class I** Medical Device*

(non-sterile, without measuring function)

*(this Declaration **expires on 30/06/2023** when CE marking is no longer recognised in Great Britain)*

Manufacturer:	POD ACTIVE Pty. Ltd.
Address:	Level 3, 115 Myers Street Geelong, Victoria 3220 AUSTRALIA
UK Representative (UKRP):	Wellkang Ltd (www.CE-marking.eu) 16 Castle St, Dover, CT16 1PW, **England**

We, the manufacturer, declare under our sole responsibility that

	Product Name	Type/model, identification of product allowing traceability (Where applicable)
the medical device(s)	Please refer to attached list	
of class	according to annex IX of directive 93/42/EEC :	**Class I** Medical Device (non-sterile, without measuring function)

is/are in conformity with the relevant provisions and essential requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC, as transposed into UK legislation (UK Medical Devices Regulations 2002 S.I. No. 618, as amended).

Conformity assessment procedure	**Module A (EC Declaration of Conformity (Annex VII) + Technical Files)**
Notified Body (name & number)	**NOT applicable**
Certificate & number	

Signed on: **Friday, 14 May 2021.** Place: **Geelong, Victoria, AUSTRALIA**

Signature (on behalf of the manufacturer)

Name of authorized signatory: **Brett Nicholas**

Position held in the company: **CEO**

POD Active Pty. Ltd.
Medical Device Registration | May 2021

Product List

Product Name (Device Make)	Model	Class**	Directive* (Regulation)
POD K4 2.0 KNEE BRACE	POD K4 2.0 KNEE BRACE	1	MDR
POD K8 2.0 KNEE BRACE	POD K8 2.0 KNEE BRACE	1	MDR
CTi MISSION 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	1	MDR
POD A3 ANKLE BRACE	POD A3 ANKLE BRACE	1	MDD
DonJoy Performance POD® Ankle Support Brace	DonJoy Performance POD® Ankle Support Brace	1	MDD

***** The applicable directive must be either **MDD** or **IVDD**.

****** Under the **MDD** (i.e. directive 93/42/EEC), the class must be either **I** (Class I, non-sterile, without measuring function), **Is** (Class I, sterile), **Im** (Class I, with measuring function), **IIa, IIb** or **III**, and/or **future UK relevant legislation**
****** Under the **IVDD** (i.e. directive 98/79/EC), the class must be either **List A, List B, Self-Test,** or **Others,** and/or **future UK relevant legislation**

The classification is based on the claim of the manufacturer and is under the sole responsibility of the manufacturer.