Declaration of Conformity

Manufacturer	Orthomobility Ltd (Company number 5143375)
Manufacturer address	E1.29 Culham Science Centre, Abingdon, OX14 3DB, United Kingdom
Basic UDI-DI	506077798VGKPROXIMAL6F
Name and trade names of the device(s)	Product name: *VGK100* Trade names: *VGK-S or Very Good Knee - Short Transfemoral*
Intended purpose	The VGK100 is intended to be solely used in lower extremity prosthetic limbs as a prosthetic knee joint.
Classification	Class I, non-measuring, non-sterile
Conformity assessment route	Orthomobility uses the conformity assessment procedure appropriate for the device classification. The procedure is the drawing up of technical documentation showing compliance with the requirements of the *UK MDR 2002*, and the issuing of this declaration of conformity.

This declaration of conformity is issued under the sole responsibility of Orthomobility Ltd. We hereby declare that the medical device(s) specified above meet the provision of **The Medical Devices Regulations 2002**. This declaration is supported by the Quality System approval to **ISO 9001:2015** as issued by the British Assessment Bureau, and Structural testing of lower-limb prostheses to **ISO 10328:2016**.

Name:
Jacob Boender
Function:
Technical Director of Orthomobility
Place and date (dd.mm.yyyy) of issue:
15.03.2022, Culham, UK

Signature:

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