EU Declaration of Conformity

Manufacturer	Orthomobility Ltd (Company number 5143375)
Manufacturer address	Culham Science Centre, Abingdon, OX14 3DB, United Kingdom
Single Registration Number (SRN)	*Not available until the EUDAMED system is fully operational.*
Authorised Representative Name	MDSS GmbH
Authorised Representative Address	Schiffgraben 41 30175 Hannover, Germany
Basic UDI-DI	506077798VGK-XHM
Name and trade names of the device(s)	Product name: *VGK080* Trade names: *VGK-X or VGK-XS*
Intended purpose	The VGK080 is intended to be solely used in lower extremity prosthetic limbs as a prosthetic knee joint.
Classification	Class I, non-measuring, non-sterile (in accordance with the rules set out in *Regulation MDR 2017/745 Annex VIII*)
Conformity assessment route	Orthomobility uses the conformity assessment procedure set out in Section 7 of Article 52 of the Regulation MDR 2017/745. The procedure is the issuing of the EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II & III.

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 **Regulation (EU) MDR 2017/745** for medical devices. 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:
Director of Orthomobility
Place and date (dd.mm.yyyy) of issue:
01.03.2022, Culham, UK

Signature:

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