



EU Declaration of Conformity

Manufacturer	Orthomobility Ltd (Company number 5143375)
Manufacturer address	Culham Science Centre, Abingdon, OX14 3DB, United Kingdom
Single Registration Number (SRN)	<i>Not available until the EUDAMED system is fully operational.</i>
Authorised Representative Name	CERTLabel UG (haftungsbeschränkt)
Authorised Representative Address	Wichertstraße 16/17 10439 Berlin, Deutschland
Basic UDI-DI	506077798VGKPROXIMAL6F
Name and trade names of the device(s)	Product name: <i>VGK100</i> Trade names: <i>VGK-S or Very Good Knee - Short Transfemoral</i>
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 (in accordance with the rules set out in <i>Regulation MDR 2017/745 Annex VIII</i>)
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:

30.12.2020, Culham, UK

Signature:

30/12/2020 Culham, UK