



## EU Declaration of Conformity

<b>Manufacturer</b>	Orthomobility Ltd (Company number 5143375)
<b>Manufacturer address</b>	Culham Science Centre, Abingdon, OX14 3DB, United Kingdom
<b>Single Registration Number (SRN)</b>	<i>Not available until the EUDAMED system is fully operational.</i>
<b>Authorised Representative Name</b>	MDSS GmbH
<b>Authorised Representative Address</b>	Schiffgraben 41 30175 Hannover, Germany
<b>Basic UDI-DI</b>	506077798VGKDISTAL22
<b>Name and trade names of the device(s)</b>	Product name: <i>VGK125</i> Trade names: <i>VGK-Go! or Very Good Knee - Go!</i>
<b>Intended purpose</b>	The VGK125 is intended to be solely used in lower extremity prosthetic limbs as a prosthetic knee joint. The VGK125 is best used for medium and long femur length in the residual limb. For short transfemoral the VGK100 is recommended.
<b>Classification</b>	Class I, non-measuring, non-sterile (in accordance with the rules set out in <i>Regulation MDR 2017/745 Annex VIII</i> )
<b>Conformity assessment route</b>	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:**