Certificate of Verification

Medical Device Safety Service GmbH (MDSS)

hereby declares that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

Regal Prosthesis Ltd.

Room 3D, Tower F, Mai Luen Industrial Bldg.

23-31 Kung Yip Street

Kwai Chung, NT

HONG KONG

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2022-02-28

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 534775

This certificate is subject to the following terms and conditions:
It is only valid for the device(s) listed hereafter;
It is not a proof for compliance to CE marking;
The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;
As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.
This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MM-DD	BfArM Registration Number*
ACE-02 Version 02	Prosthetic Feet and Adaptors (Non-implantable)	61229	I	ACE-03 Rev. 01 Signed: 23 November 2021	N.A.	N.A.	DE/CA09/00103098
		64736					
CE-02 Version V1.3	Prosthetic Knee-joints and Hip-joints (Non-implantable)	64718	I	CE-03 Vers. V1.3 Signed: 2 December 2021	N.A.	N.A.	DE/CA09/00103098
		64719					
		64727					
ICE-02 Version 0	Orthotics and Rehabilitation	36206	I	ICE-03 Ver. 0 Signed: 9 December 2021	N.A.	N.A.	DE/CA09/00185160
		41065					DE/CA09/00185161
		41575					DE/CA09/00185162
		36228					DE/CA09/00185163
HCE-02 Version 0	Prosthetic Suspension Systems (Non-implantable)	41536	I	HCE-03 Vers. 0 Signed: 9 December 2021	N.A.	N.A.	DE/CA09/00185164
		64715					DE/CA09/00185165
		64736					DE/CA09/00185166
SCE-02 Version 03	Silicone Cosmetic Prostheses	41080	I	SCE-03 Rev. 01 Signed: 1 December 2021	N.A.	N.A.	DE/CA09/00103098
		41086					
		64735					
		64736					
YCE-02 Version 0	Upper limbs prosthesis (Non-implantable)	41102	I	YCE-03 Signed: 9 December 2021	N.A.	N.A.	DE/CA09/00185167
		41489					DE/CA09/00185168

*The registration number has been issued by the German Competent Authority.