



*This is to certify that the Medical Devices Quality Management System of*

## **REGAL PROSTHESIS LIMITED**

Room 3D, Tower F, Mai Luen Industrial Bldg., 23-31 Kung Yip Street, Kwai Chung, NT, Hong Kong

(The certification locations and scopes are listed in Appendix)

*complies with the requirements of **ISO 13485 : 2016** international standard,  
applicable to:*

### **Design and manufacture of Silicone Cosmetic Prostheses Supply of Prosthetics & Orthotics products**

*The certificate remains valid subject to satisfactory maintenance of the system  
which will be monitored by Hong Kong Quality Assurance Agency.*

Signed for and on behalf of

## **HONG KONG QUALITY ASSURANCE AGENCY**

\_\_\_\_\_

**Chief Executive Officer**

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**Director**

Registered address 19/F K. Wah Centre 191 Java Road North Point Hong Kong Tel (852) 2202 9111 Fax (852) 2202 9222  
Note In accordance with the Agency Regulations, the Hong Kong Quality Assurance Agency undertakes no liability or responsibility for any product or service supplied by the organization in accordance with the requirements of this Certification Scheme. The use of the Accreditation mark(s) shown on this certificate (if applicable) indicates accreditation in respect of those activities covered by that Accreditation Authority. This certificate remains the property of HKQAA and shall be returned when required by the Agency. Further clarifications regarding the scope of this certificate and the applicability of ISO 13485 : 2016 requirements may be obtained by consulting the organization.

Date of Granting

26 September 2014

Expiry Date

27 June 2025

Effective Date (Recertification / Extension / Reduced)

28 June 2022

Amendment Date

12 May 2022