



America

# CERTIFICATE

No. QS6 103602 0003 Rev. 00

**Certificate Holder:**

**The Female Health Company (UK) Plc**  
3 Mansfield Road  
Western Avenue Business Park  
London, W3 0BZ  
UNITED KINGDOM

**Certification Mark:**



**Scope of Certificate:**

**Design, Development and Manufacture  
of Female Condoms**

**Standard(s):**

**ISO 13485:2016**

**Regulatory Authority(ies):**

**Australia TGA, Brazil ANVISA, Health Canada, USA FDA.  
See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:**

**F005610**

**Effective Date:**

**2022-03-28**

**Expiry Date:**

**2025-03-27**

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**Date of Issue:** 2022-04-26

( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services

# CERTIFICATE

No. QS6 103602 0003 Rev. 00

**Regulatory Requirements:      Audit/Certification Criteria**

**Australia**

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil**

- RDC ANVISA n. 16/2013  
- RDC ANVISA n. 23/2012  
- RDC ANVISA n. 67/2009

**Canada**

- Medical Device Regulations – Part 1- SOR 98/282

**United States**

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

**Facility(ies):**

The Female Health Company (UK) Plc  
3 Mansfield Road, Western Avenue Business Park, London, W3 0BZ,  
UNITED KINGDOM

The Female Health Company (M) Sdn Bhd  
No 1A Jalan CJ 1/4, Kawasan Perindustrian Cheras Jaya, 43200  
Balakong, MALAYSIA

**Facility Scopes:**

**The Female Health Company (UK) Plc**

3 Mansfield Road, Western Avenue Business Park, London, W3 0BZ,  
UNITED KINGDOM

Design and Development of Female Condoms  
REPs Facility ID: F005610

**The Female Health Company (M) Sdn Bhd**

No 1A Jalan CJ 1/4, Kawasan Perindustrian Cheras Jaya, 43200  
Balakong, MALAYSIA

Manufacture of Female Condoms  
REPs Facility ID: F005611

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( Renee Walker )  
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