



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
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

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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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