

**MDSAP**

Medical Device Single Audit Program



America

# C E R T I F I C A T E

No. QS6 103602 0003 Rev. 03

**Certificate Holder:**

The Female Health Company (UK) Plc  
Unit 23 Park Royal Metro Centre  
Britannia Way  
Park Royal  
London, NW10 7PA  
UNITED KINGDOM

**Certification Mark:****Scope of Certificate:**

**Design, Development, Manufacture and Distribution  
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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 103602 0003 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:QS6 103602 0003 Rev. 03)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:****F005610****Report No.:****75965453****Effective Date:****2025-10-16****Expiry Date:****2028-03-27**

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( Renee Walker )  
Director, US Certification Body, MHS



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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. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

**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**

Unit 23 Park Royal Metro Centre, Britannia Way, Park Royal, London, NW10 7PA, UNITED KINGDOM

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

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

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Director, US Certification Body, MHS

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No. QS6 103602 0003 Rev. 03

**Facility Scopes:**

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

Unit 23 Park Royal Metro Centre, Britannia Way, Park Royal,  
London, NW10 7PA, UNITED KINGDOM

Design, Development, Manufacture and Distribution of Female  
Condoms

REPs Facility ID: F005610

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

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Manufacture and Distribution of Female Condoms

REPs Facility ID: F005611

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