THE FEMALE HEALTH COMPANY (UK) PLC QUALITY POLICY STATEMENT

The Female Health Company is committed towards quality, safety, and efficacy of our manufactured medical devices. To this end, FHC is :

1) to ensure that the product is manufactured to the established standards and specifications
2) committed to its customers, the users of the product
3) to establish a workforce with qualifications
4) complying with the Quality Management System requirements and continual improvement
5) to comply with the applicable statutory and regulatory requirements and other compliance obligations

Elaborations of the Quality Policy

The Female Health Company (UK) Plc, with facilities at 3 Mansfield Road, Western Avenue Business Park, London W3 0BZ and with a manufacturing facility, The Female Health Company (M) Sdn Bhd located at No. 1A, Jalan CJ 1/4, Kawasan Perindustrian Cheras Jaya
43200 Balakong. Selangor Malaysia, is the manufacturer of a medical device, the Female Condom.

FHC Management has developed a vision and philosophy which will guide the organisation's quality efforts. The company is conversant with "Good Manufacturing Practices" and operates quality systems that are accredited to ISO13485:2016 EC Medical Devices Regulations (EU) 2017/745 and in compliance with USFDA CFR 820. The safety and efficacy of the devices is paramount. To that end, FHC Management has made a commitment to manufacturing its devices to the highest quality standards and practices in accordance with ISO 25841:2017 Requirement and test methods.

The first consideration is to **assure that the product is manufactured to the established standards and specifications**. This goal is incorporated into the company's strategic and operational planning processes. A system of management activities is established to ensure the results. Management sets quality objectives, together with a quality plan, that provides adequate resources for their implementation and reviews and monitors their effectiveness.

Second, FHC is **committed to its customers, the users of the product**. To this end, Quality Systems are in place that allow the company consistently to produce devices which are always safe and effective for intended use. Feedback from our post market surveillance is carefully monitored to assist us in improving our processes. Proactive action is taken to determine and fulfil the changing demands of our customers

Third, FHC has **established a workforce with qualifications** which are directly applicable to the manufacture of its medical devices. All employees are formally trained with emphasis on quality systems, product manufacturing, use of the device and the implementation of "good manufacturing practices" within the Quality Programme.

Fourth, FHC top management is committed to **complying with the Quality System requirements** and will **continually develop and implement improvements** to all aspects of its operations, including but not restricted to the Quality Management System, manufacturing processes and product design.

Fifth, To **comply with the applicable statutory and regulatory requirements in the markets where the product is being sold.** Further FHC will comply with recognised international standards that are applicable to the product, design, and quality management system.

29th Sept 2022

With all of the above elements in place and operational, FHC will achieve its quality goals and ultimate success in the marketplace.

Review

Suitability of the Quality Policy will be reviewed during the management review and revised as appropriate

Any revision will be displayed on both UK and Malaysian sites.

29th Sept 2022

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