ORIGINAL

STANDARD PROCEDURE

Subject: Quality Assurance & Environmental Policy No: FHC0500 Issue No: 14

Date: 06.06.16 **Supersedes:** 13 – 25.01.16

Q.A. Approval: **Date:** 7·6·16

Approved by: **Date:** 8/6/16

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. We are equally concerned about environmental protection. To this end, we are:

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) conserve resources and to prevent pollution, and to comply with the applicable environmental laws and other compliance obligations

Elaborations of the Quality and Environmental 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 ISO9001: 2015, ISO 14001: 2015, ISO13485:2016 EC Medical Devices Directive 93/42/EEC and in compliance with USFDA CFR 820. The Safety and Efficacy of the devices is paramount. To that end, FHC (UK) Management has made a

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commitment to manufacturing its devices to the highest quality standards and practices in accordance with ISO 25841:2014 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, 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 customers 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 and Environmental Management System requirements** and will **continually develop and implement improvements** to all aspects of its operations, including but not restricted to the Quality and Environmental Management System, manufacturing processes and product design.

Fifth, FHC believes in **sustainable development** in all its activities, operation and manufacturing process. FHC has established and implemented an effective Environmental Management System with the aim to conserve resources and to prevent pollution. FHC seeks to **comply with the applicable environmental laws and other compliance obligation** to safeguard the environment.

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

ISO 9001 ISO 13485

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CHANGE RECORD

Issue No.	Date	Drafted By	Reason for Change
01	10.03.93	WDC	Initial
02	14.04.93	MRS	Wording detail changes
03	15.02.95	NT	Cavendish Square address taken out
04	17.06.96	NT	Added text in paragraph 2
05	20.08.96	NT	Additional text in paragraph 2
06	21.10.97	NT	Doc: 063. Company Name Change
07	02.12.97	NT	Doc: 067. Para 2 change in text
08	12.11.02	NT	Doc: 158. Additional text to 3rd and 4th paragraph, date changed in paragraph 2.
09	05.01.05	NT	Doc:178 Amend ISO reference
10	16.01.07	NT	Doc:194 Amend to include Malaysia production
11	04.02.11	NT	Doc: 226 Update ISO ref, Malaysia and UK address, and re-number and re-name
12	13.11.14	NT	Doc 256 Include FHC M address and continuous improvement
13	25.01.16	MK	Doc 261 Include Environmental aspects
14	06.06.16	SS	Doc 264 Update ISO 9001, 13485 ref

ISO 9001 ISO 13485