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Zentralstelle der Länder
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bei Arzneimitteln und
Medizinprodukten
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BS-MDR-099



Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 103602 0002 Rev. 00

Manufacturer:

The Female Health Company (UK) Plc

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

SRN Manufacturer:

Not available at issuance date of this certificate

Authorized Representative:

Advena Limited
Tower Business Centre, 2nd Flr, Tower Street, BKR 4013 Swatar,
MALTA

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 103602 0002 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10_103602_0002_Rev._00)

Report No.:

75950573

Valid from:

2022-07-21

Valid until:

2027-07-20

Christoph Dicks

Issue date: 2022-07-21

Head of Certification/Notified Body



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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 103602 0002 Rev. 00

Classification:	IIb
Device Group:	U110203 - FEMALE CONDOMS
Intended Purpose:	A single use, non-sterile barrier contraceptive device and to help prevent the transmission of sexually transmitted infections. For vaginal use only.

The validity of this certificate depends on conditions and/or is limited to the following: ./.