DNV

EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
7168GB448240116	7168AU11F	2024-01-16	2027-04-12

This is to certify that the quality system of

BioClin B.V.

Blaak 555, 3011GB Rotterdam, The Netherlands
SRN: NI-MF-000006004

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapters I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-01-16

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Certificate no.: 7168GB448240116
Place and date: Hamburg, 2024-01-16

Preceding certificate

Certificate no.	Issue date	Identification of changes
N/A	N/A	N/A

Sites covered by this certificate

BioClin B.V., Blaak 555, 3011GB Rotterdam, The Netherlands

Certificate no.: 7168GB448240116
Place and date: Hamburg, 2024-01-16

Products covered by this certificate

Class IIb medical devices, excluding implantable non-WET*

Category	EMDN code	Medical devices/groups of medical devices
MDN 1213	U0803	VAGINAL DEVICES IN THE FORM OF SOLUTIONS/CREAMS/OVA/TABLETS

Intended purpose

- Treatment and relieve of vaginal dryness
- Relief of vaginal yeast symptoms
- Treat Bacterial Vaginosis and related symptoms and discomforts

* WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.