

EU Quality Management System Certificate BE26/00000093

The management system of

Gynetics Medical Products N.V.

Rembert Dodoensstraat 51, 3920 Lommel, Belgium
SRN Number: BE-MF-000024832

has been assessed and certified as meeting the requirements of
**MDR (EU) 2017/745 Quality Management System certificate (Annex IX
Chapter I and III)**

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 01 April 2026 until 01 April 2031 and remains valid subject to satisfactory surveillance audits.

Recertificate audit due before 01 October 2030

Issue 1. Certified since 01 April 2026



Authorised by

Virginie Siloret

Head of Certification and
Compliance

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EU Quality Management System Certificate BE26/00000093,
continued

Gynetics Medical Products N.V.

SGS

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class Is devices

MDN1212, MDS1005
Sterile Endometrial Curette (sampling)
[Basic UDI-DI: 540700389ENDOCUR0168]
Sterile Embryo Transfer Catheter
[Basic UDI-DI: 540700389ETC012D]
Sterile Intrauterine Insemination Catheter/Cannula
[Basic UDI-DI: 540700389IUI014W]

MDN1202, MDS1005
Sterile GIS (gel instillation sonohysterography) Catheter
[Basic UDI-DI: 540700389GIS0136]

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Certification is based on following reports: - BE/AND/09307 - S2A 1.1 + TFR 1.2

Authorized representative name and address (if relevant): N/A

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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