

The management system of

Gynetics Medical Products N.V.

Rembert Dodoensstraat 51
3920 Lommel, Belgium

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

For the following products

- Sterile endometrial curette (sampling)
- Sterile embryo transfer catheter
- Sterile intra-uterine insemination catheter
- Sterile GIS catheter: gel instillation sonohysterography catheter

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 04 September 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 30 January 1999
and first certified by SGS Belgium NV since 31 October 2019

Certification is based on reports numbered BE/AND/ 09307

Authorised by

SGS Belgium NV, Notified Body 1639

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LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01

Page 1 of 1

