EC Certificate – Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V
Certificate No. MDD-124

Issued to:	MedGyn International, Inc. 100 West Industrial Road, USA-60101 ADDISON (IL), USA
Product category:	Gynecology sampling devices
GMDN:	Endosampler - 32594 / Aspiration Kit - 32594/ Collection set, Vacuum curette – 32594 Cell Sweep – 32368
Product category:	Pipette
GMDN:	32594
Product category:	HSG Catheter, sterile
GMDN:	15622

SIQ has audited the quality system in accordance with MDD Annex V, restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions and found that the above-mentioned manufacturer's quality system meets the requirements of the Directive 93/42/EEC concerning medical devices Annex V, including all subsequent amendments. This certificate is based on

Audit report No.:
OSV 01562/2019, 2020-01-31
OSV 00308/2020, 2020-04-29
OSV 01498/2020, 2021-01-27
OSV 01616/2020, 2021-01-27
OSV 00073/2021, 2021-03-23
OSV 00581/2021, 2021-05-14

See also decision of NB`s commission for medical devices.

This certificate remains valid as long as the Manufacturer's quality system is subject to periodical surveillance as referred to in Directive 93/42/EEC concerning medical devices Annex V (4), restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions, and continues to meet the above requirements.

Certification date: 2019-02-12

Issue: 2/2021-05-21

Valid until: 2024-05-26

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