MedGyn

DECLARATION OF CONFORMITY

We, **MEDGYN PRODUCTS, INC.** is located 800 Pasquinelli Dr.Westmont, IL 60559. USA.as the Product Owner, hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Medical Device Regulations in Vietnam according to the Ministry of Health (MOH).

Name and Address of Product Owner:

MEDGYN PRODUCTS, INC. is located at 800 Pasquinelli Dr.Westmont, IL 60559. USA.

Name and Address of Physical Manufacturer:

MEDGYN PRODUCTS, INC. is at 800 Pasquinelli Dr.Westmont, IL 60559. USA.

Name and Address of Authorized Representative:

Hemotek Joint Stock Company : No. 19/154 Cho Kham Thien Str, Kham Thien Wd, Dong Da Dist., Hanoi, Vietnam

Medical Device(s):

Product(s)	Models
MedGyn Endosampler	022720,022722, 022720L, 022720XL
MedGyn Pipette	022721,022730,022734
HSG Catheters	022726, 022728, 022726-K, 022728-K
MedGyn Intrauterine Inseminator Catheter	022723, 022724, 022725
Disposable Insemination Kit with HSG Catheter	022799
Disposable Insemination Kit with EZ Inject Catheter	022800
MedGyn Follicle Aspiration Needle	022699
MedGyn Embryo Transfer Catheter	022698
MedGyn Vitrification Straws	022697
MedGyn Aspiration Kit Double Valave	022526
MedGyn Laminaria	021002-021010, 021033-021035
MedGyn Uterine Manupulator	022700, 022701

MedGyn Baloon Catheter	022703
MedGyn Cell Sweep	022361, 022363
MedGyn Uterine Sounds	020250
MedGyn Word Bartholin Catheter	022719

Risk Classification:

Class 1

Quality Management System Certificate:

- Certificate Name: ISO13485:2016, Certificate Body: Intertek Testing Services NA,Inc., Certificate Number: 0072858-05, Issue Date: 2024-03-04, Expire date: 2027-03-04

Standards Applied:

1. EN ISO 13485:2016- Medical Devices - Quality Management Systems–Requirements for Regulatory Purposes.
2. EN ISO/TR 14969:2004 - Medical Devices-Quality Management Systems–Guidance on the Application of ISO 13485:2003
3. EN ISO 14971:2019 - Medical Devices - Application of Risk Management to Medical Devices
4. SOR/98-282 – Canadian Medical Device Regulations
5. MDD 93/42 EEC – Medical device directive (European Union)
6. DIN EN 556-1 - Sterilization of Medical Devices - Requirements for Medical Devices to be Labeled 'Sterile'. Part 1: Requirements for Terminally Sterilized Medical Devices.
7. BS EN ISO 10993-1:2009 - Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process.
8. ISO 10993-5:2009--Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.
9. ISO 10993-10:2010 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
10. EN ISO 10993-7:2008-Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008).
11. EN ISO 11607-1:2009- Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)
12. ANSI/AAMI/ISO 11607-2:2006 Packaging for terminally sterilized medical devices— Part 2: Validation requirements for forming, sealing, and assembly processes.
13. EN 1041:2008-Information supplied by the manufacturer with medical devices.
14. MEDDEV. 2.7.1 -Clinical evaluation: A guide for manufacturers and notified Bodies.
15. ANSI/ASQ Z 1.4- Sampling procedures and tables for inspection by attributes
16. 21CFR820-Good Manufacturing Practices for Medical Devices - General

17. ANSI/AAMI/ ISO 15223-1:2012 Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements American National Standard Licensed.
18. ISO 11737-1: 2006 Sterilization of medical devices Microbiological methods —Part 1: Determination of a population of microorganisms on products.
19. ISO 11737-2:2009 - Sterilization of medical devices -Microbiological methods - Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process.
20. ISO 14937:2009 Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.
21. ISO/TR 16142 -Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices.
22. EN62366:2015 - Application Usability Engineering to Medical Devices
23. ASTM 4169-05 - Standard Practices for Performance Testing of Shipping Containers and Systems
24. NB-MED/2.7/Rec3 - Evaluation of Clinical data
25. ISO 14644-1 Clean rooms and associated controlled environments —Part 1: Classification of air cleanliness by particle concentration.
26. ISO 14644-2 Clean rooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.
27. ISO11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.

This declaration of conformity is valid from 14 March 2025

Authorized Signatory:

Dr. Amar Agadi. M.D
Chief Medical Officer
VP – Operations /Quality & Regulatory Affairs

14 March, 2025

MEDGYN PRODUCTS, INC. · 800 Pasquinelli Drive · Westmont, IL 60559 · MedGyn Products, Inc.