

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## MedGyn Products International Inc. and MedGyn Products, Inc.

(FIN F000887)

Main Site: 800 Pasquinelli Drive

Westmont, Illinois, 60559, United States

has been registered by Intertek, an MDSAP recognised auditing organisation,  
as conforming to the requirements of:

### ISO 13485:2016

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

**Brazil:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

**Canada:** Medical Devices Regulations – Part 1- SOR 98/282

**United States:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

### The management system is applicable to:

The design and manufacture of colposcopes, reusable instruments, vaginal pessaries, and sterile single use disposables for the area of gynecology. The design and manufacture of cryosurgical equipment and tips, fetal monitors, dopplers, electrosurgical equipment and post-partum balloon catheters. The distribution of pumps and ultrasounds.

**Certificate Number:**

0072858

**Revision Level:** 06

**Initial Certification Date:**

2018-03-05

**Certification Effective Date:**

2025-02-12

**Certification Expiry Date:**

2027-03-04



intertek

A handwritten signature in black ink, appearing to read 'Rathin Grover', is written over a horizontal line.

**Rathin Grover**

President, Business Assurance

Intertek Testing Services NA, Inc.  
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