

## **DECLARATION OF CONFORMITY**

**Manufacturer:**  
(Name and Address) : **MedGyn International Inc.**  
100 W. Industrial Rd.  
Addison, IL 60101  
USA

**Authorized EC Representative**  
(Name and Address) : **MEDICAL CENTAR D.O.O (EU)**  
Karlovacka Cesta 4c  
10 000 Zagreb  
Croatia

**Product name** : Uterine Sampling Devices

**Product Categories** : Endosampler I & II, Aspiration Kit, Tissue Collection Set, Rigid Curved  
Curettes, Rigid Straight Curettes, Flexible Curettes, Pipette, Cell  
Sweep (Reference numbers and sizes: Refer -DOC Appendix -A)

**Classification** : Class Is, Rule 1 of Annex IX of MDD 93/42/EEC

I, the undersigned, hereby declare and am authorized to certify that the Medical Device(S) specified above meet the provisions of Directive 93/42/EEC (MDD) which apply to them, as transported into the national laws of the EU member states. In addition, I declare that our product meets the provisions as laid out under Annex I of the Essential Requirements as required under the same directive.

This declaration is supported by the MDD, Annex V Approval CE Certificate number MDD-124, dated 02.12.2019 issued by SIQ, Notified Body, number 1304, SIQ Ljubljana, Trzaska cesta 2, SI-1000 Ljubljana, Slovenija.

Date of Issue/Update of Declaration : May 04, 2022

Signed by Name: Amar Agadi Title: Vice President Operations

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**DOC- Appendix- A ( Product Categories)**

**ENDOSAMPLER /ASPIRAITON KIT**

Ref #	Product Description
022720	MedGyn Endosampler
022722	MedGyn Endosampler
022514	MedGyn Aspiration Kit with 4mm Cannula
022515	MedGyn Aspiration Kit with 5mm Cannula
022516	MedGyn Aspiration Kit with 6mm Cannula
022517	MedGyn Aspiration Kit with 7mm Cannula
022511	MedGyn Aspiration Kit IV with 4mm, 5mm, 6mm and 7mm Cannula-Curette
022526	MedGyn Aspiration Kit Double Valve

**TISSUE COLLECTION SET**

Ref #	Product Description
022310	3/8" Collection Set with Handle & Adaptor
022310-L	3/8" Collection Set with Handle & Adaptor <b>(Loose)</b>
022310-50	3/8" Collection Set with Handle & Adapter
022310-WO	3/8" Collection Set with Handle (Without Adapter)
022314	3/8" Collection Set x 8 Ft with Handle & Adaptor
022312	½" Collection Set with Handle & Adaptor
022312-25	½" Collection Set with Handle

**VACUUM CURETTE**

Ref #	Product Description
022106	Curette Rigid Curved 6mm
022107	Curette Rigid Curved 7mm
022108	Curette Rigid Curved 8mm
022109	Curette Rigid Curved 9mm
022110	Curette Rigid Curved 10mm
022111	Curette Rigid Curved 11mm
022112	Curette Rigid Curved 12mm

**VACUUM CURETTE**

Ref #	Product Description
022113	Curette Rigid Curved 13mm -3/8" small base
022114	Curette Rigid Curved 14mm -1/2" Large base

#### **VACUUM CURETTE**

Ref #	Product Description
022144	Curette Rigid Curved 14mm - ½" Base with Adapter
022145	Curette Rigid Curved 14mm - 3/8" Small Base
022115	Curette Rigid Curved 15mm - ½" Large Base
022116	Curette Rigid Curved 16mm - ½" Large Base
022213	Curette Rigid Straight 13mm - 3/8" Base
022214	Curette Rigid Straight 14mm - ½" Base
022244	Curette Rigid Straight 14mm - ½" Base with Adapter
022245	Curette Rigid Straight 14mm - 3/8" Base
022215	Curette Rigid Straight 15mm - ½" Base
022216	Curette Rigid Straight 16mm - ½" Base

#### **VACUUM CURETTE**

Ref #	Product Description
022206	Curette Rigid Straight 6mm
022207	Curette Rigid Straight 7mm
022208	Curette Rigid Straight 8mm
022209	Curette Rigid Straight 9mm
022210	Curette Rigid Straight 10mm
022211	Curette Rigid Straight 11mm
022212	Curette Rigid Straight 12mm
022004	Curette Flexible 4mm - w/ Dual Port Design
022005	Curette Flexible 5mm - w/ Dual Port Design
022006	Curette Flexible 6mm - w/ Dual Port Design
022007	Curette Flexible 7mm - w/ Dual Port Design
022008	Curette Flexible 8mm - w/ Dual Port Design
022009	Curette Flexible 9mm - w/ Dual Port Design
022010	Curette Flexible 10mm - w/ Dual Port Design
022011	Curette Flexible 11mm - w/ Dual Port Design
022012	Curette Flexible 12mm - w/ Dual Port Design

#### **CELL SWEEP**

Ref #	Product Description
022361	MedGyn Cell Sweep Non Sterile
022363	MedGyn Cell Sweep Sterile

**PIPETTE**

Ref #	Product Description
022721	MedGyn Pipette 3.1mm O.D.
022734	MedGyn Pipette II 3.1mm O.D.
022730	MedGyn Pipette IV 3.1mm O.D.