biogYn S.r.l.
Medical Devices

DECLARATION OF CONFORMITY

Manufacturer:	Biogyn S.r.l. Unipersonale Via A. Volta, 14 41037 Mirandola (Mo) - Italy Tel. +39.0535.26889 - Fax +39.0535.21975
European representative	Not applicable
Medical device:	**GIMABRUSH** **Personalized brush for taking cytologic endocervical samples- GIMA**
REF	**EBR2 S01 (sterile)**
Classification:	**I sterile –** According to Rule 5 of Annex IX of MDD.

Biogyn s.r.l. declares, under its own total responsibility, that the products indicated in the present document are in compliance with applicable and essential requirements described in the Annex I of the European Directive on Medical Devices.

All the relative documentations are collected in a technical file and kept by Manufacturer.
This document is drawn in compliance with the Annex V + VII of MDD.

Following the provisions of Directive:	Directive 93/42/EC concerning medical devices, accepted in Italy with D.Lgs.46/97 and modified by the Directive 2007/47/EC, (accepted in Italy with D. Lgs.37/10).
In conformity with EC Council Standards:	EN ISO 13485, EN ISO 11135, EN556, and with all Standards shown in the Essential Requirement Check-list
Notify body:	**KIWA CERMET ITALIA S.p.A.** Via Cadriano, 23 40057 Cadriano di Granarolo (BO)
EC Certificates No. :	**MED 31546 e**xpiry **26/05/2024**
The device was CE marked starting on:	01/07/1998

Place and date:	Mirandola, 21/06/2021
Signature:	_____
Surname, name (Authorized person):	Lin Lin
Function	General Manager