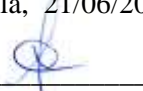


DECLARATION OF CONFORMITY

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:	ENDO GYN Microcurette for taking hystologic and cytologic endometrial and endocervical sample.
REF	END1 S01 (sterile)
Classification:	I sterile – According to Rule 5 of Annex IX of MDD.
<p>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.</p> <p>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.</p>	
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
Notified body:	0476 - KIWA CERMET ITALIA S.p.A. Via Cadriano, 23 40057 Cadriano di Granarolo (BO)
EC Certificates n. :	MED 31546 expiry 26/05/2024
The device was CE marked starting on:	29/06/1998
Place and date:	Mirandola, 21/06/2021
Signature:	
Surname, name (Authorized person):	Lin Lin General manager

BIOGYN S.r.l. Unipersonale

Sede legale e amministrativa: 41037 Mirandola (Mo) - Via A. Volta, 14 - Tel (+39)053526889 - Fax (+39)053521975
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