

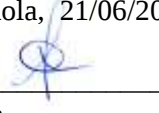
DECLARATION OF CONFORMITY

Manufacturer:	Biogyn S.r.l. Unipersonale Via A. Volta, 14 41037 Mirandola (Mo) - Italy Tel. +39.0535.26889 - Fax +39.0535.21975
Medical device:	CANNULA RIGIDA DRITTA – RIGIDA CURVA Straight and curved rigid cannula-curette for intrauterine aspiration and for voluntary abortion
European representative	Not applicable
REF	See the attached list of references.
Classification:	IIa – 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 II 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, EN 556, and with all Standards shown in the Essential Requirement Check-list.
Notified body:	KIWA CERMET ITALIA S.p.A. Via Cadriano, 23 40057 Cadriano di Granarolo (BO)
EC Certificate No. :	MED 31546A expiry 26/05/2024
The device was CE marked starting on:	21/10/1999

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

BIOGYN S.r.l. Unipersonale

Sede legale e amministrativa: 41037 Mirandola (Mo) - Via A. Volta, 14 - Tel (+39)053526889 - Fax (+39)053521975
Codice Fiscale e Partita IVA e n. Iscrizione Registro Imprese Modena 03810250369 – MO 419616
www.biogyn.it – E-mail: biogyn@biogyn



ELENCO CODICI CANNULA RIGIDA DRITTA – RIGIDA CURVA
REF. STRAIGHT AND CURVED RIGID CURETTE INDEX
Technical File 02

REF. Articolo/Item	Descrizione/Description
CRD07 S01	Cannula rigida dritta - Straight rigid curette (Ø 07 mm) - (sterile)
CRD08 S01	Cannula rigida dritta - Straight rigid curette (Ø 08 mm) - (sterile)
CRD09 S01	Cannula rigida dritta - Straight rigid curette (Ø 09 mm) - (sterile)
CRD10 S01	Cannula rigida dritta - Straight rigid curette (Ø 10 mm) - (sterile)
CRD11 S01	Cannula rigida dritta - Straight rigid curette (Ø 11 mm) - (sterile)
CRD12 S01	Cannula rigida dritta - Straight rigid curette (Ø 12 mm) - (sterile)
CRD14 S01	Cannula rigida dritta - Straight rigid curette (Ø 14 mm) - (sterile)
CRD16 S01	Cannula rigida dritta - Straight rigid curette (Ø 16 mm) - (sterile)
CRC07 S01	Cannula rigida curva - Curved rigid curette (Ø 07 mm) - (sterile)
CRC08 S01	Cannula rigida curva - Curved rigid curette (Ø 08 mm) - (sterile)
CRC09 S01	Cannula rigida curva - Curved rigid curette (Ø 09 mm) - (sterile)
CRC10 S01	Cannula rigida curva - Curved rigid curette (Ø 10 mm) - (sterile)
CRC11 S01	Cannula rigida curva - Curved rigid curette (Ø 11 mm) - (sterile)
CRC12 S01	Cannula rigida curva - Curved rigid curette (Ø 12 mm) - (sterile)

Data/Date __16/07/2021__

Firma/Signature _____



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