

EU - DECLARATION OF CONFORMITY

Manufacturer: SRN – UE Manufacturer Registration Headquarter	Biogyn S.r.l. Unipersonale IT-MF-000033403 Via A. Volta, 14 I - 41037 Mirandola (Mo) Tel. +39.0535.26889 - Fax +39.0535.21975
European representative	Not applicable
Medical device:	STICK COTTON BH Cotton big head applicator swab for cleaning, wipe, application of solutions STICK COTTON SH Cotton small head applicator swab for cytological endocervical sampling and for cleaning, wipe, application of solutions REF See attached list (not sterile)
Classification (REG. EU 2017/745):	I -non sterile , according to the Rule 5 of Annex VIII of EU MDR 2017/745.

We declare, under our own total responsibility, that the product indicated in the present document is a medical device, and it is in compliance with the General Safety and Performance Requirements described in the Annex I of the European Medical Device Regulation 2017/745.


The manufacturer undertakes to keep the technical documentation at the disposal of the competent authorities at its headquarters for a period of 10 (ten) years from the placing on the market of this device.

The conformity assessment procedure was carried out according to annexes II and III of the EU MDR 2017/745.

Following the provisions of Directive:	European Medical Device Regulation 2017/745
In conformity with EC Council Standards:	EN ISO 13485 – Quality Management System UNI EN ISO 14971:2020- Application of risk management to medical devices UNI EN ISO 10993-1:2021 - Biological evaluation of medical devices EN 15223-1:2021 - Symbols to be used with information to be supplied by the manufacturer
The device was CE marked starting on:	16/06/1998

Basic UDI-DI:	805697735004JQ
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Place and date:	Mirandola, 30/09/2024
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Signature:	
Surname, name (Authorized person):	Lin Lin
Function:	Legal representative

**ELENCO CODICI STICK COTTON NON STERILE/
NON STERILE STICK COTTON CODE LIST**

REF. Articolo/ PRODUCT REF.	Descrizione / Description
STK3 N100	Stick cotton SH - Tampone a testa piccola – non sterile- Small Head swab
STK1 N50	Stick cotton BH - Tampone a testa grossa – non sterile- Big Head swab
STK1 N25	Stick cotton BH - Tampone a testa grossa – non sterile- Big Head swab

Data__30/09/2024__

Firma_____