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: **REF**	**SPATOLA** Spatula for taking endocervical cytologic samples (Pap test) **SPA1 N100 (not sterile) - SPA1 N25 (non sterile)**
Classification (REG. EU 2017/745):	**I – Not 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:	15/10/2000
Basic UDI-DI:	805697735000JG
Place and date:	Mirandola, 30/09/2024
Signature: Surname, name (Authorized person): Function:	 Lin Lin Legal representative