CellPath Ltd
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EU DECLARATION OF CONFORMITY – *CERVIBRUSH*

Date: 06/09/2022

This Declaration of Conformity has been issued solely by CellPath Limited (Company Number 01831261) in accordance with the definitions and regulations as described in the **EU Regulation 2017/745 of The European Parliament and of the Council on Medical Devices**.

General Information

Manufacturer	CellPath Limited
Address of Production Facility	CellPath Ltd (GB-MF-000022744) Unit 80, Mochdre Enterprise Park Newtown, Powys Mid Wales, UK SY16 4LE
EU Authorised Representative	EMERGO EUROPE (NL-AR-000000116) Prinsessegracht 20 2514 AP The Hague The Netherlands
Product Name	Cervical Cytology Brush
Product Description	A device with bristle-like projections designed to obtain a cervical biopsy of a suspicious area or visible exocervical lesions detected during a vaginal examination for the purpose of obtaining a tissue diagnosis from a woman with intraepithelial disease. It is inserted into the vagina and the head of the brush is firmly rotated over the area of interest until is covered with a bloody-mucoid sample. Some types may also have small bristles on a central protrusion that simultaneously enters the endocervical canal. The sample is secured in a cytology fixation solution or smeared onto a microscope slide for a Papanicolaou test (PAP). This is a single-use device.
Product Classification *(Classified in accordance with Rule 5 MDR)*	CLASS I

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DEVICE(S) INFORMATION				
PART NUMBER	**GTIN**	**BASIC UDI-DI**	**DESCRIPTION**	**YEAR OF CE MARKING**
NCA-0422-02A	05056256119312	05056256NCA0012G	CERVIBRUSH+ PROFILE LBC - CERVICAL SAMPLER	2003
NCA-0780-01A	05056256119329	05056256NCA0012G	CERVIBRUSH+ LBC - (ENDOCERVICAL SAMPLER)	2004
NCA-0780-02A	05056256119336	05056256NCA0012G	CERVIBRUSH+ LBC - (ENDOCERVICAL SAMPLER)	2003

Conformity to the aforementioned regulation is demonstrated by the company's compliance to the following international manufacturing standard:

- **EN ISO 13485:2016** - Medical Devices, Quality Management Systems - Requirements for Regulatory Purposes

Signed on behalf of the Manufacturer	CellPath Limited
Address of Issue	CellPath Ltd Unit 80, Mochdre Enterprise Park Newtown, Powys Mid Wales, UK SY16 4LE
Date of Issue	06/09/2022
Name of Signatory	Alice Parry
Position of Signatory	Regulatory Project Manager
Signature	Alice Parry Alice Parry (Sep 6, 2022 10:19 GMT+1)

Cervibrush - Declaration of Conformity - EU

Final Audit Report 2022-09-06

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