



EU DECLARATION OF CONFORMITY

to the 2017/745 Medical Device Regulation

EC Declaration of Conformity according to the EU Directive (CE)

MANUFACTURER: SGS INC.
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Chungcheongnam-do, Republic of Korea

EUROPEAN REPRESENTATIVE: SMB EUROPE SAS
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COMMON/GENERIC NAME: Non-sterile cervical brush
TRADE/PROPRIETARY NAME: MEDICAL BRUSH
MODEL/TYPE (PRODUCT CODE): see *Appendix #1*
INTENDED PURPOSE: Non-sterile cervical brush is put in the woman's vaginal and take a sample the vagina cells.

ACTOR ID/SRN: KR-MF-000015895
UDI-DI: see *Appendix #1*
BASIC UDI-DI: 88000735NTBMR6
CLASSIFICATION: Class I device (excluding Class Is/Im/Ir devices) under Rule 5 according to Annex VIII

CONFORMITY ASSESSMENT ROUT: Annex II and III according to the Regulation MDR 2017/745

This declaration of conformity is issued under the sole responsibility of SGS INC. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485:2016 issued by Institute of Global Certification (IGC).

All supporting documentation is retained at the premises of the manufacturer.

STANDARDS APPLIED: EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7:2008/A1:2022, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN ISO 13485:2016/AC:2018, ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 20417:2021 MEDDEV 2.7/1 rev.4, MEDDEV 2.12/1 rev.8, MEDDEV 2.12/2 rev.2

NOTIFIED BODY: Not applicable for class I
IDENTIFICATION NUMBER: Technical File (No. NT-TF-001, Rev 0)
UMDN CODE AND TERM: 32368 – Cervical cytology brush
EMDN/CND CODE: U09030301 – UROGENITAL CYTOLOGY BRUSHES
IN PLACE: Nonsan-si
DATE OF ISSUE: July 06, 2022

SIGNATURE: *Kim Young Sang*
Mr. Young sang, Kim / President
On behalf of SGS INC.



SGS

Appendix #1**Model type and any other relevant UDI related information**

Model/type	UDI-DI number (GTIN-14)		Note
	GS1 Company Prefix	Model Reference	
NTBM-6422/ PAP BRUSH	088000735	08800073500009	Single unit package
NTBM-7522/PAP BRUSH	088000735	08800073500016	Single unit package
NTBM-M-253/PAP BRUSH	088000735	08800073500450	-
NTBM-M-93/PAP BRUSH	088000735	08800073500023	Single unit package
NTBM-NM-93/PAP BRUSH	088000735	08800073500467	-
NTBM-NM-94/PAP BRUSH	088000735	08800073500351	-
NTBM-7522H/PAP BRUSH (S)	088000735	08800073500474	-
NTBM-M93SH/PAP BRUSH (S)	088000735	08800073500481	-
NTBM-NM93S/PAP BRUSH (S)	088000735	08800073500498	-
NTBM-NM94S/PAP BRUSH (S)	088000735	08800073500368	-
NTBM-NM95S/PAP BRUSH (S)	088000735	08800073500504	-
NTBM-M93H/PAP BRUSH (S)	088000735	08800073500511	-
NTBM-H/PAP BRUSH (S)	088000735	08800073500528	-
NTBM-6422SH/PAP BRUSH (S)	088000735	08800073500535	-
NTBM-6422S/PAP BRUSH (S)	088000735	08800073500542	-
NTBM-7522S/PAP BRUSH (S)	088000735	08800073500283	Single unit package
NTBM-M93S/PAP BRUSH (S)	088000735	08800073500061	Single unit package
NTBM-6422H/PAP BRUSH (S)	088000735	08800073500559	-
NTBM-7522SH/PAP BRUSH (S)	088000735	08800073500566	-