



EU DECLARATION OF CONFORMITY

to the 2017/745 Medical Device Regulation

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

MANUFACTURER: SGS INC.
82-36 Sangwol-ro Sangwol-Myeon Nonsan-si
Chungcheongnam-do, Republic of Korea

EUROPEAN REPRESENTATIVE: SMB EUROPE SAS
41 Ave de la République, 94300 Vincennes, France

COMMON/GENERIC NAME: Non-sterile cervical brush
TRADE/PROPRIETARY NAME: MEDICAL BRUSH
MODEL/TYPE (PRODUCT CODE): see Appendix #1
BASIC UDI-DI: see Appendix #1
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/AC:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 13485:2016/AC:2018, ISO 14971:2019, EN ISO 15223-1:2016, 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 22, 2021

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



SGS

Appendix #1



MODEL/TYPE, UDI-DI and any other relevant UDI related information

Model/type	UDI-DI number (GTIN-14)		Note
	GS1 Company Prefix	Model Reference	
NTBM-6422/ PAPER BRUSH	088000735	08800073500009	Single unit package
NTBM-7522/PAPER BRUSH	088000735	08800073500016	Single unit package
NTBM-M-253/PAPER BRUSH	088000735	-	
NTBM-M-93/PAPER BRUSH	088000735	08800073500023	Single unit package
NTBM-NM-93/PAPER BRUSH	088000735	-	
NTBM-NM-94/PAPER BRUSH	088000735	-	
NTBM-7522H/PAPER BRUSH (S)	088000735	-	
NTBM-M93SH/PAPER BRUSH (S)	088000735	-	
NTBM-NM93S/PAPER BRUSH (S)	088000735	-	
NTBM-NM94S/PAPER BRUSH (S)	088000735	-	
NTBM-NM95S/PAPER BRUSH (S)	088000735	-	
NTBM-M93H/PAPER BRUSH (S)	088000735	-	
NTBM-H/PAPER BRUSH (S)	088000735	-	
NTBM-6422SH/PAPER BRUSH (S)	088000735	-	
NTBM-6422S/PAPER BRUSH (S)	088000735	-	
NTBM-7522S/PAPER BRUSH (S)	088000735	08800073500283	Single unit package
NTBM-M93S/PAPER BRUSH (S)	088000735	08800073500061	Single unit package
NTBM-6422H/PAPER BRUSH (S)	-	-	
NTBM-7522SH/PAPER BRUSH (S)	-	-	