EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland®

Registration No.:	DZ 2029176-1
Manufacturer:	**CITOTEST LABWARE MANUFACTURING CO., LTD.** No.339 Beihai West Road, Haimen, 226100 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000017214
Products:	Products of class I, sterile: A1101 SAMPLE COLLECTION NEUTRAL SWABS - Classical swabs - Transport swabs U089002-DEVICES FOR GYNAECOLOGICAL CYTOLOGY - Cytology brushes The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions.
Authorised representative(s):	Wellkang Ltd Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-05-30

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.:	244434755-200
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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.