EU Certificate

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

TÜVRheinland®

Registration No.:	DZ 2041633-1
Manufacturer:	**Jiangsu Rongye Technology Co., Ltd.** Touqiao Town, Yangzhou City 225109 Jiangsu P.R. China
EUDAMED Single Registration No.:	CN-MF-000019627
Products:	Products of class Is: Q0399 - ENT DEVICES - OTHERS - Otolaryngological Sets for Single Use A060304 - INTRA-OPERATION FLUID COLLECTION DEVICES - Liquid Drainage Device V0202 - UMBILICAL CLAMPS AND CLIPPERS, SINGLE-USE - Umbilical Cord Clamps for Single Use U089006 - VAGINAL SPECULUM, SINGLE-USE - Vaginal Speculums for Single Use V9001 - TONGUE DEPRESSORS, SINGLE-USE - Tongue Depressors for Single Use Q030499 - OTOLOGY DEVICES - OTHERS - Ear Checkers for Single Use A060102 - SURGICAL DRAINAGE CONNECTION MEDICAL TUBES - Medical Suction-connecting Tubes for Single Use V9012 - NON-SPECIALIST SURGICAL INSTRUMENTS AND KITS, SINGLE-USE - Plastic Forceps A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE - Urinary Drainage Bags for Single Use Q030199 - NASOPHARYNGEAL DEVICES - OTHER - Nasal Speculums A1101 - SAMPLES COLLECTION, NEUTRAL SWABS - Specimen Collection Swabs

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.:	244421417-200
Effective date:	2022-09-28
Expiry date:	2027-09-27
Issue date:	2022-09-28

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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

EU Certificate

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

TÜVRheinland®

Registration No.: DZ 2041633-1

Manufacturer: **Jiangsu Rongye Technology Co., Ltd.**
Touqiao Town,
Yangzhou City
225109 Jiangsu
P.R. China

The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions

Authorised representative(s): Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039, Spain

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2022-09-28

Report No.: 244421417-200

Effective date: 2022-09-28

Expiry date: 2027-09-27

Issue date: 2022-09-28

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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