EC CERTIFICATION

EU QUALITY ASSURANCE CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex XI Part A

We hereby declare that a conformity assessment based on a production quality assurance system restricted to the aspects of manufacture concerned with the conformity of the devices with sterility requirements - has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620185246

Revision:
00

Initial Certification Date:
27 August 2024

Date of Certification Decision:
27 August 2024

Certificate Issue Date:
27 August 2024

Certificate Expiry Date:
25 July 2029

Suzhou Riyuexing Plastic Co., Ltd.

No.9, Ximuhe Street, Huashan Road, High and New Zone, 215129 Suzhou, China

Manufacturer SRN: CN-MF-000033487

Authorised Representative Name

MedPath GmbH

Mies-van-der-Rohe-Strasse, 8 80807 Munich, Germany

Scope:

Sterility aspects of devices as detailed in attached product list.

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**Stage 1 audit ACTY-2024-179605**
	Stage 2 audit ACTY-2024-179607

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620185246

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PRODUCT LIST FOR CERTIFICATE

Issued to: Suzhou Riyuexing Plastic Co., Ltd.

Certificate number: 28620185246

Certificate valid from: 2024-08-27

Product List Issue Date:
27 August 2024

Product	Classification and EMDN	Intended use[1]	Date Added
Class I sterile devices			
Basic UDI-DI: 69215226DDBE&DSLF9			
Type I, Double chamber:1500ml - Disposable Drainage Bottle Equipment	Class I(s) A060203		2024-08-27
Type I, Single chamber:1600ml - Disposable Drainage Bottle Equipment	Class I(s) A060203		2024-08-27
Type I, Triple chamber:1500ml - Disposable Drainage Bottle Equipment	Class I(s) A060203		2024-08-27
Type II, 1000ml - Disposable Suction Liner	Class I(s) A060399		2024-08-27
Type II, 1500ml - Disposable Suction Liner	Class I(s) A060399		2024-08-27
Type II, 2000ml - Disposable Suction Liner	Class I(s) A060399		2024-08-27
Type II, 3000ml - Disposable Suction Liner	Class I(s) A060399		2024-08-27
Type II, Double chamber:1400ml - Disposable Drainage Bottle Equipment	Class I(s) A060203		2024-08-27
Type II, Double chamber:1500ml - Disposable Drainage Bottle Equipment	Class I(s) A060203		2024-08-27
Type II, Triple chamber:1300ml - Disposable Drainage Bottle Equipment	Class I(s) A060203		2024-08-27

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.