

Certificate

Quality Management System EN ISO 13485:2016

Registration No.	SX 2181632-1
Certificate Holder	Changzhou Holinx Industries Co., Ltd. No. 1 Dongtang Road, Zhenglu Town, Tianning District Changzhou 213115 Jiangsu P.R. China
Scope	Manufacture and Distribution of Syringes for Single Use, Infusion Sets for Single Use, Hypodermic Needles for Single Use, Intravenous Needles for Single Use, Vaginal Speculums for Single Use, Urine Bags for Single Use, Infusion Bags, Disposable Nebulizer Masks, Re-usable Oral Syringes(with or without Adaptors), Medical Packaging Materials

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.	244491543-200
Effective date	2023-04-16
Expiry date	2026-04-15
Issue date	2023-03-20



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

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EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60144902 0001

Report No.: 15096089 007

Manufacturer: Changzhou Holinx Industries
Co., Ltd.
No. 1 Dongtang Road
Zhenglu Town, Tianning District
Changzhou
213115 Jiangsu
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60127504 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-12-02

Date: 2019-12-02



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: DD 60144902 0001
Report No.: 15096089 007

Manufacturer: Changzhou Holinx Industries
Co., Ltd.
No. 1 Dongtang Road
Zhenglu Town, Tianning District
Changzhou
213115 Jiangsu
China

Products:

- Syringes for Single Use
- Infusion Sets for Single Use
- Hypodermic Needles for Single Use
- Intravenous Needles for Single Use

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal Speculums for Single Use
- Urine Bags for Single Use

Date: 2019-12-02





Changzhou Holinx Industries Co.,Ltd

Add: Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China.

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Changzhou Holinx Industries Co.,Ltd	Shanghai International Holding Corp. GmbH
Address: No.1 Dongtang Road, Zhenglu Town	(Europe)
Tianning District Changzhou, Jiangsu China	Address: Eiffestrasse 80,20537 Hamburg, Germany
Tel: 86 519 85619978, FAX: 86 519 86059978	Tel: +49 40 2513175 FAX:+49 40 255726
Zip Code: 213115	

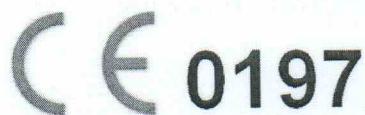
We, the manufacturer, herewith declare that the products:

Disposable syringe with needle, hypodermic needle, Infusion set

Style No.: Annex I

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex V of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: DD 60144902 0001

Issue date: 02.12.2019

Expiry date: 27.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific

Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility

Company: Changzhou Holinx Industries Co.,Ltd

Address: No.1 Dongtang Road, Zhenglu Town Tianning District Changzhou, Jiangsu
China

Signature:



Date: 8th AUG. 2022



Changzhou Holinx Industries Co.,Ltd

Add: Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China.

Annex I

Product Code	Item	Description	Samples qty (pcs)
H50I29/12	Syringe	1ml insulin syringe with fixed 29GX1/2" needle,50units	5
H100I29/12	Syringe	1ml insulin syringe with fixed 29GX1/2" needle,100units	5
H1LDS23/1	Syringe	1ml syringe fixed 23GX1" needle, low dead space(vaccine injection use)	5
H1LDS25/1	Syringe	1ml syringe fixed 25GX1" needle, low dead space(vaccine injection use)	5
H1LS25/58	Syringe	3-parts luer slip, 1ml with 25GX5/8" needle	5
H2LS23/1	Syringe	3-parts luer slip, 2ml with 23GX1" needle	5
H3LS23/1	Syringe	3-parts luer slip, 3ml with 23GX1" needle	5
H3LS23/114	Syringe	3-parts luer slip, 3ml with 23GX1 1/4" needle	5
H5LS22/114	Syringe	3-parts luer slip, 5ml with 22GX1 1/4" needle	5
H5LS22/112	Syringe	3-parts luer slip, 5ml with 22GX1 1/2" needle	5
H10LS21/112	Syringe	3-parts luer slip, 10ml with 21GX1 1/2" needle	5
H10LS22/112	Syringe	3-parts luer slip, 10ml with 22GX1 1/2" needle	5
H20LS21/112	Syringe	3-parts luer slip, 20ml with 21GX1 1/2" needle	5
H20LS20/112	Syringe	3-parts luer slip, 20ml with 20GX1 1/2" needle	5
H30LS21/112	Syringe	3-parts luer slip, 30ml with 21GX1 1/2" needle	5
H50LS18/112	Syringe	3-parts luer slip, 50ml with 18GX1 1/2" needle	5
H1LL25/58	Syringe	3-parts luer lock, 1ml with 25GX5/8" needle	5
H2LL23/1	Syringe	3-parts luer lock, 2ml with 23GX1" needle	5
H3LL23/1	Syringe	3-parts luer lock, 3ml with 23GX1" needle	5
H3LL23/114	Syringe	3-parts luer lock, 3ml with 23GX1 1/4" needle	5
H5LL22/114	Syringe	3-parts luer lock, 5ml with 22GX1 1/4" needle	5
H5LL22/112	Syringe	3-parts luer lock, 5ml with 22GX1 1/2" needle	5
H10LL21/112	Syringe	3-parts luer lock, 10ml with 21GX1 1/2" needle	5
H10LL22/112	Syringe	3-parts luer lock, 10ml with 22GX1 1/2" needle	5
H20LL21/112	Syringe	3-parts luer lock, 20ml with 21GX1 1/2" needle	5
H20LL20/112	Syringe	3-parts luer lock, 20ml with 20GX1 1/2" needle	5
H30LL21/112	Syringe	3-parts luer lock, 30ml with 21GX1 1/2" needle	5
H50LL18/112	Syringe	3-parts luer lock, 50ml with 18GX1 1/2" needle	5
HHN18/112	Needle	Hypodermic needle,18GX1 1/2"	5
HHN19/112	Needle	Hypodermic needle,19GX1 1/2"	5





Changzhou Holinx Industries Co.,Ltd

Add: Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province, China.

HHN20/112	Needle	Hypodermic needle, 20GX1 1/2"	5
HHN21/112	Needle	Hypodermic needle, 21GX1 1/2"	5
HHN22/112	Needle	Hypodermic needle, 22GX1 1/2"	5
HHN23/1	Needle	Hypodermic needle, 23GX1"	5
HHN24/1	Needle	Hypodermic needle, 24GX1"	5
HHN26/1	Needle	Hypodermic needle, 26GX1"	5
HHN27/12	Needle	Hypodermic needle, 27GX1/2"	5
HHN29/12	Needle	Hypodermic needle, 29GX1/2"	5
HHN30/12	Needle	Hypodermic needle, 30GX1/2"	5
HIVS21/112	Infusion set	luer slip, latex, 21Gx1 1/2"	5
HIVSW/O21	Infusion set	luer slip, without latex bulb, 21Gx1 1/2"	5

