



# 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                           |   |

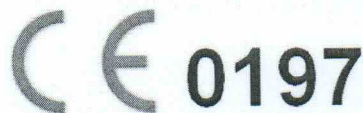
We, the manufacturer, herewith declare that the products:

**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

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### 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                 |





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|            |              |   |   |
|------------|--------------|---|---|
| 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 |

