

Changzhou Holinx Industries Co.,Ltd

No.1 Dongtang Rd.,Zhenglu Town, Changzhou, Jiangsu, China

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

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| Changzhou Holinx Industries Co.,Ltd Address: No.1 Dongtang Rd.,Zhenglu Town, Changzhou, Jiangsu, China | Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80,20537 Hamburg, Germany |
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We, the manufacturer, herewith declare that the product:

Combi stopper

GMDN Code:63614

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

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

CE 0197

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 601449020001

Issue date: 02.12.2019

Expiry date: 27.5.2024

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 Rd.,Zhenglu Town, Changzhou, Jiangsu, China

Place: Changzhou, China

Signature(General manager):



Date: 17th April. 2023