

## Declaration of Conformity

*Manufacturer:*

*whose single Authorized Representative:*

<b>Jiangsu Eyoung Medical Devices Co.,Ltd</b>	<b>Shanghai International Holding Corp. GmbH</b>
Address: No.1 Dongtang Road, Zhenglu Town	<b>(Europe)</b>
Tianning District Changzhou,213115 Jiangsu	Address: Eiffestrasse 80, 20537 Hamburg,
China	Germany

We, the manufacturer, herewith declare that the products

### **Combi stopper**

GMDN Code:63614

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

**CE 0197**

Harmonized standards: EN ISO10993, EN ISO11135-1, EN ISO11607-1, EN ISO11737-1, EN ISO11737-2, EN ISO13485, EN ISO14971, EN 20594-1, EN ISO7886-1

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 601323060001

Issue date: 27.05.2019

Expiry date: 31.12.2028

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

Date: 2024.9.10

Place: Changzhou, China

Signature (General manager)

