

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Hanzhou Hua'an Medical & Health Instruments Co., Ltd. Building 2, 1# Fuzhu Nan RD, Wuchang Town, Yuhang District 310023, Hangzhou, Zhejiang 310023, China	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg Germany
--	---

We, the manufacturer, herewith declare that the products

Product name: Disposable Cover

Type(s): IET2PC

meet the provisions of Regulation 2017/745 which apply to them.

The medical device has been assigned to class I according to Annex VIII of the Regulation 2017/745.

The product concerned has been designed and manufactured under a quality management system according to ISO 13485:2016.

Quality management system certificate:

ISO 13485 certificate

Certification body : **TÜV Rheinland LGA Products GmbH**

Tillystraße 2, 90431, Nürnberg, Germany

QMS Certificate No.: SX 2095316-1

Issue date: 26.01.2022

Expiry date: 16.02.2025

following the procedure relating to the EC Declaration of Conformity set out in Annex IV of Regulation 2017/745.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Hanzhou Hua'an Medical & Health Instruments Co., Ltd.

Address: Building 2 1# Fuzhu Nan RD, Wuchang Town, Yuhang District, 310023 Hangzhou, Zhejiang, China

Hangzhou China, February 22, 2024

