

EC Declaration of Conformity

Manufacturer:

**Hangzhou Hawk Optical Electronic
Instruments Co., Ltd.**

**Add: No.9 Xinda Road, Suoqian, Xiaoshan,
Hangzhou, Zhejiang, 311201, P.R. China**

Tel: +86 - 571 - 22811660

Fax: +86 - 571 - 22811228

whose single Authorized Representative:

**Shanghai International Holding Corp.
GmbH (Europe)**

**Add: Eiffestrasse 80, 20537 Hamburg,
Germany**

Tel: +49 - 40 - 2513175

Fax: +49 - 40 - 255726

We, the manufacturer, herewith declare that the products

Video-Cystoscope UMDNS-Code: 16331

(Code: DR060380B-2, P9440E/P9442EA, N2010A, N2020A)

meet the provisions of Directive 93/42/EEC and its transpositions in national laws which apply to it. The medical device has been assigned to class **Ila** according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a full quality assurance system according to Annex II, **excluding section 4** of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

**TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany**

Certificate No.: HD 60128006 0001

Issue date: 2018-06-29

Expiry date: 2023-6-26

following the procedure relating to the EC Declaration of Conformity set out in **Annex II, excluding section 4** of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

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

Company: Hangzhou Hawk Optical Electronic Instruments Co., Ltd.

Address: No.9, Xinda Road, Suoqian, Xiaoshan, Hangzhou, Zhejiang, 311201, P.R.China

Hangzhou,

Place, date

Q/HKA009-2016-1 V1.0

Wang Hualin (General Manager)

Legally binding signature, Function

