EC Declaration of Conformity

Manufacturer:

PENTAX-Aohua Medical Technologies Co., Ltd.
East of 3rd Floor, Block C, Building 1, No.5
Shenwang Rd., Minhang District, Shanghai
201108, China

Authorized Representative for the European Union (EU) as per the Directive 93/42/EEC:

PENTAX Europe GmbH
Julius-Vosseler-Straße 104, 22527 Hamburg, Germany
Tel: +49 (0)40 561 92-0 Fax: +49 (0)40 561 92

We, the manufacturer, herewith declare under the sole responsibility that the products

Video Gastroscopes *(EG27-V10c/EG29-V10c)*
Video Colonoscopes *(EC38-V10cM/EC38-V10cL)*
Endoscope Imaging Processors *(EPK-V1500c)*

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

The medical devices as per above list has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The products concerned has been designed and 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

following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

In addition, the aforementioned electrical-medical devices do comply with the requirements as per the Directive 2011/65/EU (RoHS II).

Digitally signed by Ceaicovschi Tudor
Date: 2022.05.20 00:47:10 EEST
Reason: MoldSign Signature
Location: Moldova

May 10, 2018
date

Arthur Dai
General Manager
PENTAX-Aohua Medical Technologies Co., Ltd.