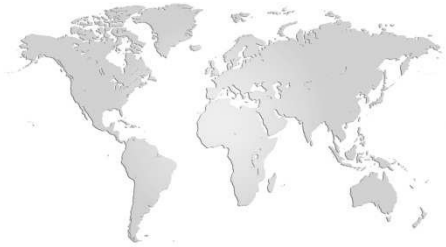
EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Ovesco Endoscopy AG

Friedrich-Miescher-Str. 9, 72076 Tübingen, Germany

Certified location:

Friedrich-Miescher-Str. 9, 72076 Tübingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50970-Z5-00, the decision dated 2018-10-23 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-05-20 to 2023-11-07

Registration No.: 50970-16-05

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565 DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-05-20
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

EC certificate_eng, Rev.2. Released 28.05.2021 via Ovesco CAQ system. Valid without signature.

Annex to the EC Certificate No. 50970-16-05

Valid from 2019-10-02 to 2023-11-07

Revision status of the annex: 2 dated 2021-04-08

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Graspers, applicator caps and brushes used in flexible endoscopy and proctology

Class II a:

- Additional working channels for endoscopes
- HemoPill acute
- HemoPill monitor
- LiftUp

Class II b:

- Clipping systems used in flexible endoscopy and proctology
- Endoscopic clipping systems with HF connection
- HF instruments
- DC instruments
- DC generators

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