EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex V

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

Atmos Medizintechnik GmbH & Co. KG

Certified location:

Ludwig-Kegel-Straße 16, 79853 Lenzkirch, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50581-Z6-00, the decision dated 2017-03-29 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-04-01 to 2020-03-31

Registration No.: 50581-17-08

DEKRA Certification GmbH Stuttgart Handwerkstraße 15 D-70565 Stuttgart

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-03-29
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

Annex to the EC Certificate No. 50581-17-08

Revision status: 2

Valid from 2017-08-22 to 2020-03-31

Devices/device categories included in the certificate:

Class Is:

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

- Canister, suction unit
- Drainage system, pleural

DEKRA Certification GmbH, D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-08-22
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