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

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 II 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 only valid in connection with the main certificate no. 50581-16-07.

This certificate is valid from 2017-05-23 to 2020-03-31

Registration No.: 50581-16-07-1

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-05-23
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. 50581-16-07-1

Revision status: 0
This annex is only valid in connection with the annex to the EC main Certificate No. 50581-16-07

Valid from 2017-05-23 to 2020-03-31

Devices/device categories included in the certificate:

Class IIa:

- ENT treatment unit
- Suction unit, tracheal
- Suction unit, transportable
- Suction unit, wound
- Suction unit, surgical, natal
- Suction unit, thoracic
- Balance test unit, vestibular stimulation
- Irrigation kit, ear
- Vacuum extractor, foetal
- Hysteroscope, rigid
- Tympanometer
- Oto-acoustic emission unit

Class IIb:

- Apparatus, cautery, radiofrequency, AC-powered

DEKRA Certification GmbH
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D-70565 Stuttgart, Handwerkstraße 15

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