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

MICON Medizintechnik GmbH

Carl-Zeiss-Straße 3, 25451 Quickborn, Germany

Certified location:

Carl-Zeiss-Straße 3, 25451 Quickborn, 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. 50301-Z6-00, the decision dated 2019-03-28 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-05-04 to 2024-05-03

Registration No.: 50301-16-06

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-28
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

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Annex to the EC Certificate No. 50301-16-06

Valid from 2019-05-04 to 2024-05-03

Revision status of the annex: 0 dated 2019-05-04

Devices/device categories included in the certificate:

Class II a:

- MD0102
  - Accessories for CO2-Insufflators
    - Reusable Tube-Sets

Class II b:

- MD1104
  - CO2-Insufflators

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

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-03-28
Notified Body ID-number: 0124

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