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

imtmedical ag

Gewerbestrasse 8, 9470 Buchs SG, Switzerland

Certified location:

Gewerbestrasse 8, 9470 Buchs SG, Switzerland

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. 50747-Z5-00, the decision dated 2018-10-26 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-10-27 to 2023-10-26

Registration No.: 50747-16-04

[redacted]

5.1.2e

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

DEKRA Certification GmbH Stuttgart; 2018-10-26
Notified Body ID-number: 0124

Annex to the EC Certificate No. 50747-16-04

Valid from 2018-10-27 to 2023-10-26

Revision status of the annex: 0 dated 2018-10-26

Devices/device categories included in the certificate:

Class II b:

- Medical compressored air compressors for connection to artificially respiration and anesthesia devices
  Type name:
  - aeris™
  - EVair
- Ventilators (invasive and non-invasive)
  Type name:
  - bellavista 1000
  - bellavista 1000e
  - bellavista 1000 neo

5.1.2e

DEKRA Certification GmbH, Stuttgart, 2018-10-26
Notified Body ID-number: 0124