EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60149031 0001

Report No.: 21273496 008

Manufacturer:
VacuTec Meßtechnik GmbH
Dornblüthstr. 14 a
01277 Dresden
Deutschland

Products:
Detectors and systems for the detection and measurement of ionizing radiation

(see attachment for products included)

Replaces Certificate, Registration No.: HD 60127716 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-28

Date: 2020-04-28

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60149031 0001
Report No.: 21273496 008

Manufacturer: VacuTec Meßtechnik GmbH
Dornblüthstr. 14 a
01277 Dresden
Deutschland

Products included:

- Ionization chambers for automatic X-ray exposure control

For the following devices the scope covers only the aspects of manufacture concerned with conformity of the products with the metrological requirements:
- Dose area product meters

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-04-28

Dipl.-Ing. I. Munkler