TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60106418 0001

Report No.: 21176351 007

Manufacturer:
GILUPI GmbH
Hermannswerder 20 a
14473 Potsdam
Deutschland

Products:
- Detector CANCER01
- Detector CANCER02 EpCAM
(see attachment for sites included)

Replaces Certificate, Registration No.: DD 60090300 0001

Expiry Date: 2017-06-20

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2016-02-05

Date: 2016-02-05

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.: DD 60106418 0001
Report No.: 21176351 007

Manufacturer: GILUPI GmbH
Hermannswerder 20 a
14473 Potsdam
Deutschland

Site included:

- GILUPI GmbH
  Walther-Rathenau-Str. 49a
  17489 Greifswald
  Germany

Notified Body

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2016-02-05