EC Certificate

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

Registration No.: HD 60102944 0001

Report No.: 21235254 001

Manufacturer:
Visage Imaging GmbH
Lepsiusstr. 70
12163 Berlin
Deutschland

Products:
Picture Archiving and Communication Systems (PACS), Advanced Visualization Software and Thin Client/ Server Solutions

(see attachment for products included)

Replaces certificate, registration no.: HD 60102335 0001

Expiry Date: 2020-07-26

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: 2015-07-27

Date: 2015-07-27

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 60102944 0001
Report No.: 21235254 001

Manufacturer:
Visage Imaging GmbH
Lepsiusstr. 70
12163 Berlin
Deutschland

Products included:

- Visage 7
  Picture Archiving and Communication System (PACS)
  including Advanced Visualization Clinical Options
  - 3D Option
  - Cardiac Analysis Option
  - Neuro Option
  - Oncology Option
- MagicWeb
- Visage Ease Pro

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2015-07-27

Dipl.-Ing. I. Munkler