



Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 09 04 43379 009

Manufacturer: Steinhart Medizinsysteme GmbH

Grubstr. 6-8
79279 Vörsstetten
GERMANY

Facility(ies):

Steinhart Medizinsysteme GmbH
Grubstr. 6-8, 79279 Vörsstetten, GERMANY

**Product
Category(ies):**

**Picture Archiving and
Communication Systems with
Image Enhancement Function**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 71349670

Valid until: 2014-04-20

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Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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