



Product Service

EC - CERTIFICATE

Full Quality Assurance System

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

No. G1 09 11 69194 002

Manufacturer: medigration GmbH
Schuhstr. 30
91052 Erlangen
GERMANY

Facility(ies): medigration GmbH
Schuhstr. 30, 91052 Erlangen, GERMANY

Product Category(ies): Software for digital X-Ray
Systems and Picture Archiving and
Communication Systems (PACS)

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.

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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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