

Certificate

Quality Assurance

ecm hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of DIN EN ISO 9001 / DIN EN 46001.

Through an audit performed on behalf of

Hospimedical GmbH

at the manufacturing site

Hüttenstr. 7, D-52068 Aachen

it could be demonstrated that a quality assurance system

according **DIN EN 46001**

to

"special requirements for the application of

DIN EN ISO 9001"

for the **design, production and sale of medical devices**

has been established and implemented.

This certificate is only valid under the conditions stated in the hereafter mentioned audit report. Any substantial changes of the quality assurance have to be notified to ECM and are subject to a separate assessment.

Report Number
Z140_001021

Registered under
Z/03/00419

Valid until
31.03.2004

Aachen, 2003-01-13


Lead Auditor


Certification Body



Certificate

Full Quality Assurance System Approval Annex II.3 of the Directive on Medical Devices

ECM notified to EC under **0481** hereby declares that an examination of the under mentioned quality assurance system has been carried out following the requirements of annex II.3 of the Directive 93/42/EEC.



This certificate is issued on behalf of:

Manufacturer

Hospimedical GmbH

Hüttenstr. 7, D-52068 Aachen

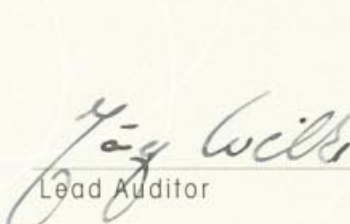
ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II.3 of the Directive 93/42/EEC on medical devices.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

| Report Number | Registered under | Valid until |
|---------------|------------------|-------------|
| Z140_001021 | Z/03/00418 | 13.01.2008 |

Aachen, 2003-01-13


Lead Auditor


Certification Body



ZLG-ZQ-926 94.06

Annex I of Certificate Z/03/00418

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This certificate is valid for the hereafter following devices:

| Name of product category | Name of individual type | Nomenclature code ¹ |
|---------------------------------|---|--------------------------------|
| Non-active implantable products | Implant for the reduction of stomach volume | / |

Special terms of validity:

None.

¹ UMDS Code is optional