

DEKRA Certification

CERTIFICATE

for the

Quality Assurance System



As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for design, manufacture and final inspection by the company

te me na SAS
16, rue des entrepreneurs (ZI des Amandiers)
F – 78420 Carrières sur Seine

Approval is based on the result of the certification audit with report number 50803-Z2-00 and is performed in accordance with the stipulations of

Annex II, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex II, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.



Date of the first certification: 17.06.2002

This certificate is valid until: 16.06.2012

Date of the last recertification: 17.06.2007

Certificate-registration No.: 50803-16-02
English version

DEKRA Certification GmbH
Stuttgart, 17.06.2007



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-992.94.16

Annex to the Certificate 50803-16-02 dated 17.06.2007

English version

Revision status: 0

Date: 17.06.2007

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Devices/device categories included in the certificate

Class II a:

- Lumbar puncture and spinal needles anaesthesia
- Epidural needles and sets
- Stimulation needles and sets
- Subcutaneous needles

Class III:

- Continuous spinal epidural anaesthesia (spinolong)



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