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# 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 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 V, 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 V, 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: 25.10.2006

This certificate is valid until: 16.06.2012

Date of the last recertification: 17.06.2007

Certificate-registration No.: 50803-17-01  
 English version

*Handwritten signature*

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 50803-17-01 dated 17.06.2007

English version

Revision status: 0

Date: 17.06.2007

Page 1 of 1

## Devices/device categories included in the certificate

### Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Syringes



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