**Inquiry on a quotation**
for a certification acc. to ISO 13485 and / or
for surveillance of certificates issued acc. to. Medical Device Directive 93/42/EEC (MDD)

SLG Prüf- und Zertifizierungs GmbH

## INFORMATION ON THE COMPANY

Company: _____

Street, number: _____

Postal code, city/town: _____

Contact person: _____

E-mail: _____

Phone: _____

Fax: _____

Company proprietor: _____

Branch offices / locations (with address): _____

Fields of business / commercial register entry: _____

Manufacturer code / DIMDI code: _____

## INFORMATION ON THE RANGE OF PRODUCTS

Product designation: _____ UMDNS code or MD scope: _____

Product description: _____

(Please enclose advertising/ information material.)

Number of generic product groups: _____

Medical field of application: _____

Risk class acc. to MDD Annex IX: Class I

Classification rule: _____

Is animal tissue rendered nonviable utilized? ☐ yes ☐ no

Is a pharmacologically active substance used in a product? ☐ yes ☐ no

Does a license exist for this product? (Please enclose license.) ☐ yes ☐ no

A product assessment is required: ☐ yes ☐ no

Product assessments are available for the following products: _____

A product assessment is required for the following products
(clinical evaluation, risk analysis, standard conformity test, EMC measurement/evaluation, type examination): _____

## DESIRED CONFORMITY ASSESSMENT OR CERTIFICATION PROCEDURE

☐ DIN EN ISO 13485 Exclusions: _____

Outsourced processes: _____

Additionally, a certification according to ISO 9001:2008 is required: ☐ yes ☐ no

Desired scope: _____

## INFORMATION ON THE QUALITY ASSURANCE SYSTEM

**Current status**

A QM/ QA system has been implemented: ☐ yes ☐ no

Initial certification: ☐ yes ☐ no

Re-certification: ☐ yes ☐ no

Please, enclose a copy of the certificate and the last audit report.

☐ acc. to DIN EN ISO 9001 ☐ acc. to DIN EN ISO 13485 ☐ acc. to MDD Annex

**Documentation**

☐ one quality manual and the same process instructions for all locations
☐ one quality manual, but different process instructions for different locations
☐ different quality manuals and different process instructions for the different locations

Do you make use of consultancy services regarding your QM system? ☐ yes ☐ no

**Business locations related to the product**

Is the whole company to be audited? ☐ yes ☐ no

Which divisions are not to be certified? _____

Please, enclose the organizational chart.

| Number of employees in / location: | 1. Headquarters | 2. Production facility |
|---|---|---|
| Development | | |
| Manufacturing | | |
| Quality assurance | | |
| Regulatory affairs | | |
| Customer services | | |
| Material / purchasing / logistics | | |
| Distribution | | |
| Administration | | |

| | |
|---|---|
| Number of suppliers associated with the product<br>(Supplier: supplies assemblies / components acc. to his own specifications): | |
| Number of subcontractors<br>(Subcontractor: supplies services, assemblies / components acc. to the specifications of the manufacturer): | |

| | Company address / company profile | Kind of involvement<br>(e.g. certified, audited by the client, included in the client's QA, incoming goods inspection, ...) |
|---|---|---|
| Quality assurance/ testing | | |
| Development | | |
| Documentation | | |
| Manufacturing | | |
| Assembly | | |
| Sterilization | | |
| Software development | | |
| Others | | |

The undersigned is authorised to submit this inquiry on behalf of the inquiring company.

Place, date

Authorised representative of the inquiring company