



## Questionnaire for the Preparation of a Quotation

### Details of the Company

|                                 |   |
|---------------------------------|---|
|                                 | Main site (address for the certificate) |
| Company (Name and Legal Entity) |   |
| Street                          |   |
| Postal Code, Place              |   |
| Country                         |   |
| Homepage                        |   |
| E-Mail-Address (Company)        |   |
| Phone (Switchboard)             |   |
| Fax (Company)                   |   |
| Company VAT (TVA) ID number     |   |
|                                 |   |
| Contact person (Name)           |   |
| Position                        |   |
| Direct phone                    |   |
| Direct fax                      |   |
| Mobile phone                    |   |
| Personal E-Mail-Adress          |   |

### Subsidiaries, branch offices, production sites and further sites which are covered by the quality system

| Location | Address and legal entity | Number of Employees |                     |        |          | Shift work               |
|----------|--------------------------|---------------------|---------------------|--------|----------|--------------------------|
|          |                          | Fulltime employees  | Part time employees | Others | Trainees |                          |
| 1        |                          |                     |                     |        |          | <input type="checkbox"/> |
| 2        |                          |                     |                     |        |          | <input type="checkbox"/> |
| 3        |                          |                     |                     |        |          | <input type="checkbox"/> |
| 4        |                          |                     |                     |        |          | <input type="checkbox"/> |
| 5        |                          |                     |                     |        |          | <input type="checkbox"/> |
|          | Total                    |                     |                     |        |          |                          |

(Please copy this page in case there are more than 5 sites)

### Details of shift work (only if applicable)

|                        |                          |                      |  |
|------------------------|--------------------------|----------------------|--|
| 2-Shift operation      | <input type="checkbox"/> | Number of Employees: |  |
| 3-Shift operation      | <input type="checkbox"/> | Number of Employees: |  |
| Other shift work model | <input type="checkbox"/> | Number of Employees: |  |



# Questionnaire for the Preparation of a Quotation

## Structure of personnel (Please add an organization chart of your company)

| Business area                          | Number of employees / Location |   |   |   |   |
|--|--------------------------------|---|---|---|---|
|  | 1                              | 2 | 3 | 4 | 5 |
| Design and development                 |                                |   |   |   |   |
| Production and warehouse               |                                |   |   |   |   |
| Reprocessing of medical devices        |                                |   |   |   |   |
| Quality management and quality control |                                |   |   |   |   |
| Marketing, sales and field service     |                                |   |   |   |   |
| Administration and others              |                                |   |   |   |   |
| Total                                  |                                |   |   |   |   |

## Short description of the company's activities and branch:

|  |
|--|
|  |
|  |
|  |

## Information on your existing quality system

|   |                              |                             |
|---|------------------------------|-----------------------------|
| Is your quality system accredited?<br>(If yes, please add copies of your certificates!) | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| Are you interested in a <b>pre-audit</b> ?  | <input type="checkbox"/> yes | <input type="checkbox"/> no |
| <b>Possible date</b> for the audit?   |                              |                             |
| In which languages can the audit be conducted?  |                              |                             |

## Aimed Scope of Certification

|                          | Standard  | Accreditation/Acceptance                           |
|--------------------------|---|--|
| <input type="checkbox"/> | EN ISO 13485  | ZLG <sup>1</sup>                                   |
| <input type="checkbox"/> | EN ISO 13485 with reprocessing of medical devices (RKI <sup>2</sup> ) (see annex III)   | ZLG <sup>1</sup>                                   |
| <input type="checkbox"/> | EN ISO 13485 with additional acceptance in Taiwan   | under the TCP <sup>3</sup>                         |
| <input type="checkbox"/> | EN ISO 13485 with additional acceptance in Canada   | In co-operation with DQS <sup>4</sup>              |
| <input type="checkbox"/> | EN ISO 9001   | DAkKS <sup>5</sup>                                 |
| <input type="checkbox"/> | EN ISO 15378  | DAkKS <sup>5</sup>                                 |
| <input type="checkbox"/> | Certification of medical devices according to the European Medical Device Directive 93/42/EEC (please also fill in Annex I of this document)  | ZLG <sup>1</sup>                                   |
| <input type="checkbox"/> | Certification of in-vitro diagnostic devices according to the European IVD Directive 98/79/EC (please also fill in Annex II of this document) | ZLG <sup>1</sup>                                   |
| <input type="checkbox"/> | Audit according PAL (for acceptance in Japan – Products of class 2)   | In co-operation with Nanotec Spindler <sup>6</sup> |

## Area of aimed certification

|                          |                                 |
|--------------------------|---------------------------------|
| <input type="checkbox"/> | the whole company               |
| <input type="checkbox"/> | the following particular parts: |

Place, date

Signature or name (in case of electronic transfer)

<sup>1</sup> Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten

<sup>2</sup> RKI-Empfehlung: "Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten."

<sup>3</sup> Technical Cooperation Programme on Exchange of Medical Device GMP and ISO 13485 Audit Reports

<sup>4</sup> DQS Medizinprodukte GmbH

<sup>5</sup> DAkKS – Deutsche Akkreditierungsstelle GmbH - German Association for Accreditation GmbH

<sup>6</sup> Nanotec Spindler Co. Ltd., Nanotechno Plaza, 572-61 Toyofuta, Kashiwa-City, Chiba-Prefecture, Japan 277-0872



## Questionnaire for the Preparation of a Quotation

**(ANNEX I) Details of the Medical Devices,**  
 a certification according to EC-Directive 93/42/EEC is intended

**Devices or device categories**

|   | Name / intended use / short description of the product<br>(Please add detailed product information (e. g. instructions for use)) | Class | Rule | OEM <sup>7</sup>         |
|---|--|-------|------|--------------------------|
| 1 |  |       |      | <input type="checkbox"/> |
| 2 |  |       |      | <input type="checkbox"/> |
| 3 |  |       |      | <input type="checkbox"/> |
| 4 |  |       |      | <input type="checkbox"/> |
| 5 |  |       |      | <input type="checkbox"/> |

Please copy this page if there are more than 5 products within the certification scope

**Are these devices...**

| Characteristics   | Device                   |                          |                          |                          |                          |
|---|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|   | 1                        | 2                        | 3                        | 4                        | 5                        |
| sterile medical devices (sterilization by moist heat - EN ISO 17665)  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| sterile medical devices (sterilization by ethylene oxide – EN ISO 11135)  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| sterile medical devices (sterilization by irradiation – EN ISO 11137)   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| sterile medical devices (other sterilization methods)   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| active medical devices (driven by energy)   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| medical devices with a measuring function   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| medical devices incorporating a drug  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| medical devices incorporating materials of animal origin  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| medical devices manufactured and incorporating materials with origin of species bovine, sheep, goat, deer, elk, mink or cat | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

**Information concerning subcontractors/suppliers, if applicable**

(Please add copies of the suppliers'/subcontractors' certificates!)

|   | Name and address of subcontractors/suppliers | Subcontracted activity |
|---|--|------------------------|
| 1 |  |                        |
| 2 |  |                        |
| 3 |  |                        |
| 4 |  |                        |
| 5 |  |                        |

Please copy this page if more than 5 subcontractors are involved

<sup>7</sup> Products placed under your own name on the market but produced by other companies

**(ANNEX II) Details of the In-Vitro Diagnostic Devices,**  
a certification according to EC-Directive 98/79/EC is intended

**Devices or device categories**

|   | Name / intended use / short description of the product<br>(Please add detailed product information (e. g. instructions for use)) | Classification | OEM <sup>8</sup>         |
|---|--|----------------|--------------------------|
| 1 |  |                | <input type="checkbox"/> |
| 2 |  |                | <input type="checkbox"/> |
| 3 |  |                | <input type="checkbox"/> |
| 4 |  |                | <input type="checkbox"/> |
| 5 |  |                | <input type="checkbox"/> |

Please copy this page if there are more than 5 products within the certification scope

**Are the abovementioned products**

| Classification   | Device                   |                          |                          |                          |                          |
|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
|  | 1                        | 2                        | 3                        | 4                        | 5                        |
| Devices for self-testing   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Devices for blood glucose determination (for self-testing)   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Reagents and reagent products, including related calibrators and control materials,  |                          |                          |                          |                          |                          |
| for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for determining the following blood groups: anti-Duffy and anti-Kidd   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for determining irregular anti-erythrocytic antibodies   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for diagnosing the following hereditary disease: phenylketonuria   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for determining the following human infections: cytomegalovirus, chlamydia   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for determining the following HLA tissue groups: DR, A, B  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| for determining the following tumoral marker: PSA  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| and software, designed specifically for evaluating the risk of trisomy 21  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

**Information concerning subcontractors/suppliers, if applicable**

(Please add copies of the suppliers'/subcontractors' certificates!)

|   | Name and address of subcontractors/suppliers | Subcontracted activity |
|---|--|------------------------|
| 1 |  |                        |
| 2 |  |                        |
| 3 |  |                        |
| 4 |  |                        |

Please copy this page if more than 4 subcontractors are involved

<sup>8</sup> Products placed under your own name on the market but produced by other companies

### (ANNEX III) Details of the reprocessing of medical devices

Information concerning the reprocessing methods (e. g. Decontamination (EN ISO 15883-1 ff.), Steam sterilization (EN ISO 17665-1 ff., Sterilization by ethylene oxide (EN ISO 11135-1 ff.), H<sub>2</sub>O<sub>2</sub> – Plasma sterilization (EN ISO 14937-1 ff.) etc....)

|   | Type of reprocessing-/cleaning-/sterilization process | Number of devices/areas |
|---|---|-------------------------|
| 1 |   |                         |
| 2 |   |                         |
| 3 |   |                         |
| 4 |   |                         |
| 5 |   |                         |
| 6 |   |                         |
| 7 |   |                         |
| 8 |   |                         |

### Information concerning the classification of risk according RKI-Guidelines:

Please indicate the classification of risk of the medical devices to be reprocessed

critical A:     critical B:     critical C :

|   | critical C – devices | Reprocessing intended by manufacturer?                   | Reprocessing-/Sterilization method |
|---|----------------------|--|------------------------------------|
| 1 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 2 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 3 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 4 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 5 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 6 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 7 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 8 |                      | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |

### Other devices (not critical C):

|   | Devices | Reprocessing intended by manufacturer?                   | Reprocessing-/Sterilization method |
|---|---------|--|------------------------------------|
| 1 |         | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 2 |         | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |
| 3 |         | <input type="checkbox"/> yes <input type="checkbox"/> no |                                    |