Inquiry

The inquiry serves to get to know your business. The information contained therein will be used by the TUV NORD Polska Certification Body to prepare an offer for the certification process. We try to get to know your business as best as possible so that the prepared offer meets your expectations and complies with the guidelines in force in our Unit. Preparation of an offer based on this inquiry is free of charge and does not oblige you to use our services. Please send the completed inquiry to the address [oferta@tuv-nord.pl](mailto:oferta@tuv-nord.pl).

**GENERAL INFORMATION ABOUT THE COMPANY**

|  |  |
| --- | --- |
| **Company’s registered name:**  *click and type* | **Contact person :** *click and type*  **Phone no:** *click and type* **e-mail:** *click and type* |
| **Street, postal code, city/town:** *click and type*  **Province:** *click and type* | **Quality Manager :** *click and type*  **Phone no.:** *click and type* **e-mail:** *click and type* |
| **VAT No:** *click and type* | **www:** *click and type* **Fax no.:** *click and type* |

**SUBJECT OF THE COMPANY’S ACTIVITY**

Proposed scope of certification ISO 13485: *click and type*

Medical devices groups, services provided in the organization (concerns ISO 13485): *click and type*

Proposed scope of certification ISO 9001: *click and type*

Proposed scope of certification will be confirmed by auditors during the audit.

Polish Classification of Activities – PKD: *click and type*

# CLASSIFICATION BASIS

|  |  |
| --- | --- |
| **ISO 9001** | **ISO 13485** |

**QUOTATION**

The quotation should include the following:

Certifyingaudit, according to standard: *click and type:*

Re-certifyingaudit, according to standard: *click and type:*

Surveillance audit, according to standard: *click and type:*

Suggested tentative audit date:

**yes** date: click and type date **no**

**EMPLOYMENT INFORMATION**

**locations covered by the certification system**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| The total number of locations  *click and type:* | **Localisation I**  **Headquarters** | **Localisation II** | **Localisation III** | **Localisation IV** | **Total** |
| Name of company/plant/branch | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Address (street, postal code, town/city) | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| **Implemented processes / activities in connection with the scope of the management system**  (For information service personnel organization) please mention service multipurpose, e.g. customer support service. | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| **Total number of people employed in the area covered by certification**  (full time equivalent) | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| **Employees carrying out repetitive work - please provide the amount and type of work performed** (e.g. drivers, traders, programmers, office workers, security workers, call center, production workers - turners, welders, construction workers, garment workers, etc.) | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| **Seasonal workers / subcontractors / performing work on the basis of specific / commission contracts** (if they were included in the scope of certification**). - please provide the number of people and the type of work (duration of their employment in a year) -** if applicable | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| **In the case of a shift work system, please provide the number of employees on each shift converted into full-time jobs and information which activities resulting from the scope of activity are performed on each shift** | | | | | |
| Number of employees on 1st shift/ scope of activities | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| 2nd shift/ scope of activities | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| 3nd shift/ scope of activities | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |

*If the organisation has more localisations, please copy and fill in the table for all localisations*

# MULTISITE CERTYFICATION

### If there are affiliates/branches/plants (data for complex certification):

the company has headquarters where certain activities are planned, supervised and managed, as well as the network of local offices or affiliates (branches) where these activities are performed fully or partially

all the branches are legally or contractually connected with headquarters and covered by a common system of quality management established and supervised by the headquarters

products/services provided by all the branches are “in principle” of the same type, manufactured “in principle” with the same methods, according to the same procedures

# MANAGEMENT SYSTEMS CERTIFICATION

Please tick appropriate items characterising your activity and support briefly your answer

|  |  |
| --- | --- |
| **not applicable requirements of ISO 9001, please tick, if any:**  **8.3** research and development  **other:** *click and type:*  **not applicable requirements of ISO 13485, please tick, if any:**  **7.3** research and development | **the company has a certificate from a different independent certifying or controlling body\***  - organization issuing the certificate (name, expiration date): *click and type:*  \* If you wish to transfer certificate from another Certification Body (belonging to MLA), please send a copy of the certificate(s) together with a report from the last audit. |
| small localisation of the company as compares with the number of employees (e.g. office complex, the company does not have any branches, the company is located on one site  *click and type:* | the company has an accreditation of another body in the industry *click and type:* |
| the company runs a temporary activity (e.g. construction works) please state the average time of a year *click and type:*  the number of on-going project *click and type:* | extensive localisation – complicated logistics including more than one building (it is necessary to move among districts, municipality, towns/cities  *click and type:* |
| there are virtual locations (network environment) in which the work is performed or performed services for clients *click and type:* | **v**ery large site comparing to number of personel  (e.g., a forest). |
| processes in the company are related to one main activity *click and type:* | production processes are complicated, complex and consist of a big number of non-standard activities, there are considerable hazards as well as a high proportional share of particularly exposed employees |
| identical activities performed in all shifts in case of shift-work system | high level of automation in implemented process |
| where staff include a number of people who work “off location” e.g. salesperson, drivers, service personnel. Please give number of employees *click and type:* | significant part of company's staff perform simple, repetitive tasks (for example, in transport, at work tape, on assembly lines, performing administrative tasks, etc.) |
| **h**igh degree of regulation (e.g. food, drugs, aerospace, nuclear powerg.etc) *click and type:* | the staff speaks a few languages – there is a necessity to interpret during the audit *click and type:* |

# INFORMATION RELATING TO THE SUBCOTRACTOR

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does the company outsource important stages of design/production to other companies? If so, how the supplier is associated with your quality system? (audit with the supplier, relationship with your quality system, a pre-inspection of materials received from suppliers, certification to ISO 9001, EN 13485 and MDD)  **yes,** if yes please fill in below table  **no**  Whether the subcontractors are certified according QMS ISO 13485 in terms of the processes subcontractor (required): | | | | |
| **Proces** | **The scope of subcontracted processes in relation to the submitted products** | **Name of the Supplier / address** | **Does the subcontractor have a certificate for subcontracted processes. If so, please provide details / send a copy** | **Final control - what kind and where it takes place** |
| Design: | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Elements of production process | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Elements of production process | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Elements of production process | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Packing | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Sterilisation | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Service | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Equipment, Accessories | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Warehousing | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Labeling | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Other | *click and type:* | *click and type:* | *click and type:* | *click and type:* |

**ADDITIONAL INFORMACTION**

While implementing the systems, did you use the services of external consultants?

|  |  |
| --- | --- |
| **yes,** specify who: *click and type:* | **no** |

How did you find us: *click and type:*

Your remarks, wishes: *click and type:*

Hereby I declare that the personal data included in this inquiry have been gathered and transmitted in accordance with the applicable rules on the protection of personal data.

|  |  |  |
| --- | --- | --- |
| *click and type*  Name of a person  filling in the questionnaire | *click and type date*  Date | Signature |

***NOTE:*** In case of medical devices certification, the inquiry form and appendices should be signed and submitted to the notified body in non-editable form (pdf, scan, fax)

**Thank you for filling in the request for quotation form.**

*Please send the completed inquiry to address* ***oferta@tuv-nord.pl*** *or fax: +48 32 786 46 02.*

*Visit us on the Web*

[**www.tuv-nord.pl**](http://www.tuv-nord.pl)