Initial Inquiry form

This initial inquiry is used to get to know the activities of your company. The data and information you provide have an impact on the determination and justification of the audit time. The time of the audit will be sent to you as part of the initial valuation. We try to get to know your business as best as possible to be sure that the prepared preliminary valuation meets your expectations and complies with the applicable guidelines for Certification Bodies. Preparing an initial valuation on the basis of this inquiry is free of charge and does not oblige you to use our services. Please send the completed inquiry to [mdd@tuv-nord.pl](mailto:mdd@tuv-nord.pl)

# NOTE: The Notified Body does not conduct conformity assessments of medical devices of territory on the United States and Canada. Certification of any new quality management system requires additional specific information. In this case, we will ask you to complete the necessary information.

**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*  **Country:** *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**

Medical devices scope submitted for conformity assessment according to MDR 2017/745*)*: *click and type*

This scope will appear on the first page of the certificate

Medical devices submitted for conformity assessment according to MDR 2017/745: *click and type*

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.

# Conformity Assessment Procedures

|  |  |  |
| --- | --- | --- |
| **Quality Management System Certification by Certification Body TÜV NORD Polska** | **Medical Device Certification by Polish Notified Body TÜV NORD Polska no. 2274** | **Length of certification period\*** |
| PN-EN ISO 9001:2015 | MDR 2017/745, Annex IX for clases Is, Im, Ir, IIa, IIb, III | 3 years |
| PN-EN ISO 13485:2016 | MDR 2017/745, Annex XI p. 10 for clases IIa | 5 years |
|  | MDR 2017/745, Annex XI part A for clases Is, Im, Ir | Other….. (no longer than 5 years) |
|  | MDR 2017/745 Article 16 a) translating information provided by producer |  |
|  | MDR 2017/745 Article 16 b) changes in outer packaging |  |
|  | MDR 2017/745 Opinion of Notified Body on conformity of parts constituting medical device  ( Article 117). |  |

*\* In case of:*

*- ISO 13485 or 9001 - always 3 years*

*- MDR + ISO – we recommend 3 years*

*- MDR without ISO – we recommend 5 years*

**QUOTATION**

The quotation should include the following:

Certifyingaudit, according to standard: *select item*

Re-certifyingaudit, according to standard: *select item*

Surveillance audit, according to standard: *select item*

MDR 2017/745 Article 16 a) translating information provided by producer

MDR 2017/745 Article 16 b) changes in outer packaging

MDR 2017/745 Opinion of Notified Body on conformity of parts constituting medical device ( Article 117).

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:* |
| Type of activities performed (processess) | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Total number of employees including contract and seasonal employees - full time equivalent of the above:  **- MDR 2017/745, EN ISO 13485**  **- ISO 9001** | *click and type:*  *click and type:* | *click and type:*  *click and type:* | *click and type:*  *click and type:* | *click and type:*  *click and type:* | *click and type:*  *click and type:* |
| **Employees carrying out repetitive work - please specify number and type of work performed** ( ex. drivers, sales , programmers, office workers, security, call center, production workers) | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| Number of employees on 1st shift | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| 2nd shift | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* |
| 3nd shift | *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 (7.3 for ISO 13485)** research and development  **8.5.1f (for ISO 9001)** process validation  **8.5.3 (for ISO 9001)** customer’s property  **other:** *click and type:* | **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.) |
| OBL producer  In the case of OBL producer certification, Notified Body requires the customer to provide a complete technical product documentation. | the staff speaks a few languages – there is a necessity to interpret during the audit *click and type:* |
| **h**igh degree of regulation (e.g. food, drugs, aerospace, nuclear powerg.etc) *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, ISO 13485 or MDR / MDD). It concerns also OEM subcontractors.  **yes,** if yes please fill in below table  **no**  Do subcontractor has certyficate quality managnet system according ISO 13485  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** | **Declared medical device** | **Technology  MDT / MDS Code** |
| Design: | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |
| Elements of production process | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |
| Elements of production process | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |
| Elements of production process | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDS CODE  MDT CODE  MDS CODE |
| Packing | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |
| Sterilisation | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |
| Service | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDS CODE  MDT CODE  MDS CODE |
| Accessories | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |
| Warehousing | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |
| Labeling | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDS CODE  MDT CODE  MDS CODE |
| Other | *click and type:* | *click and type:* | *click and type:* | *click and type:* | *click and type:* | MDT CODE  MDT CODE  MDS CODE |

**RISK ACTIVITIES**

Please specify the level of business risk:

High risk - where failure of the product or service causes economic catastrophe or puts life at risk.

Medium risk - where failure of the product or service could cause injury or illness.

Low risk - where failure of the product or service is unlikely to cause injury or illness.

In the past, it happened to your product, service caused and any of the above threats?

**no,**  **yes,** please specify:*click and type:*

In the last certification cycle happened to your product, service has been withdrawn from the market?

**no,**  **yes,** please specify:*click and type:*

**INTEGRATED SYSTEMS CERTYFICATION**

In the case of the integrated systems certification, please tick the items which will help to define the integration level of your management systems. Ticking all the items means full integration of implemented systems.

Management reviews taking into consideration general business strategy and plan

Integratedapproach to internal audits

Integratedapproach to policy and objectives

Integratedapproach to systemic processes

Integratedset of documentscoveringworkinginstructions, on a good level of development, according to a situation

Integratedapproach to improvement mechanisms (corrections and corrective actions; surveying and continuous improvement)

Integratedapproach to planning with a good use of comprehensive approach to risk management in business

Unified support and managerial responsibility

Systems audit performed: jointly separately

**ADDITIONAL INFORMATION**

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.**

*Visit us on the Web*

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