**1. Details about the company and contact person (a potential client)**

|  |  |
| --- | --- |
| **Company:** | . |
| Address: |  |
| Homepage: |  |

|  |  |
| --- | --- |
| **Contact person:**  |  |
| Phone: |  |
| Fax: |  |
| E-mail: |  |

**2. List of the specified products with classification**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Products(+ intended use) | EC Directive | Tissues of animal origin used? | Does product contain nanoparticles < 100 nm? | Sterile? \* | Invasive device? | Classification + rules (MDD) |
|  |  |  |  | [ ]  yes[ ]  no | [ ]  yes[ ]  no |  |
|  | MDD | IVDD |  |  | Steam | ETO | Irradiation | Other | Implant | Short-term | Long-term |  |
| 1 |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 2 |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 3 |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 4 |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 5 |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| Human blood derivatives used? | [ ]  yes | [ ]  no |
| Integrated medicinal substance used? | [ ]  yes | [ ]  no |
| \* Is the sterilization process validated with the specified products? | [ ]  yes | [ ]  no |
| If yes, is the sterilization performed in house? | [ ]  yes | [ ]  no |
| Do you maintain Cleanroom conditions?If yes, which classification (acc. EN ISO 14664)? | [ ]  yes | [ ]  no |

*For more information visit:* <http://www.nbog.eu/resources/NBOG_BPG_2009_3.pdf>, <http://www.itczlin.cz/cz/MD-legislation>

|  |  |  |
| --- | --- | --- |
| Do you sell products under your own company name, which are produced by the other company (OEM – OBL)? | [ ]  yes | [ ]  no |
| If yes, did the original equipment manufacturer (OEM) already carry out a conformity assessment procedure? |  [ ]  yes |  [ ]  no |

|  |  |  |
| --- | --- | --- |
| Do any quality management system (QMS) certificates for your company already exist?If yes, which QMS is implemented? |  [ ]  yes |  [ ]  no |
|  |

*Please enclose copies of already existing QM system certificates.*

**3. Desired conformity assessment procedure**

|  |  |
| --- | --- |
| **MDD** (93/42/EEC)EC directive on medical devices | **IVDD** (98/79/EC)EC Directive on in vitro diagnostics |
| [ ]  Annex II, excl. point 4[ ]  Annex II, point 4[ ]  Annex V[ ]  Annex VI | [ ]  Annex III, point 6[ ]  Annex IV, excl. points 4+6[ ]  Annex IV, point 4[ ]  Annex V[ ]  Annex VI[ ]  Annex VII |

*Please mark relevant Annexes.**For more information visit* <http://www.newapproach.org>

|  |
| --- |
| Further international approvals already granted: |
| [ ]  PAL GMP (Japan)[ ]  FDA[ ]  TCP Taiwan[ ]  Other (please specify) |

*Please enclose copies of already existing authority approvals for other than European market(s).*

**4. Details about your quality system**

|  |  |
| --- | --- |
| Please specify the scope of your quality system (QS), as stated in your quality manual: |  |
| Activities excluded from the scope of the QS:(*Please mark if applicable*) | [ ]  Production[ ]  Design and Development |
| Did you receive consultancy regarding the implementation of your QS? | [ ]  yes, by:[ ]  no |

|  |  |  |  |
| --- | --- | --- | --- |
| Please specify the (approximate) numbers of employees in the particular departments**Name and address of the headquarters, as well as of the possible subsidiaries / branches** | **Departments** | **Sum** | Number of shifts |
| Quality Management | Design and Development | Purchasing | Production | Warehouse | Sales | Service | Other |
|  |  |  |  |  |  |  |  |  |  |  |
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| --- |
| **Please specify all appropriate Production Technologies applicable to your device(s)** |
| Joining technologies (special processes which require validation, e.g. welding, gluing, brazing and soldering) | [ ]  | Textile/fiber processing, weaving technologies (bandages, wound dressings, implants) |[x]
| Polymer processing (extrusion, injection moulding for plastics, wound dressing, etc.) |[ ]  Biotechnology manufacturing techniques (pharmaceuticals, medicine, reagents) |[ ]
| Metal (machining, grinding, cutting, finishing, etc.) |[ ]  Manufacturing techniques for ceramics |[ ]
| Thin and thick film manufacturing (electronic devices such as surface mount devices, sensors, and printed circuit boards) |[ ]  Micro precision manufacturing processes (for precise devices such as catheters, bone screws, micromechanics and optics) |[ ]

|  |  |
| --- | --- |
| **Processes** | **Name and location of subcontractors which perform outsourced processes** |
| Design and Development |  |
| Production |  |
| Packaging |  |
| Sterilization |  |
| Warehouse |  |
| Service |  |
|  |  |

**5. Controlled environmental conditions / specification about your products**

|  |  |  |
| --- | --- | --- |
| Do you manufacture under defined environmental conditions? | [ ]  yes | [ ]  no |
| If yes, which parameters or certain areas are controlled and monitored? |
| [ ]  Temperature[ ]  Humidity[ ]  Total particle counts[ ]  Microbial counts | [ ]  ESD controlled areas[ ]  Radiation protected areas[ ]  Others:  |

**6. Time scale/scheduling**

|  |  |
| --- | --- |
| Please specify your desired dates for: |  |
| the product testing / product documentation review: |  | the audit: |  |

**7. Product tests**

Please mark for which product tests we may offer additional information to you.

|  |
| --- |
| [ ]  Electric safety test[ ]  EMC test[ ]  Other: |

|  |
| --- |
| **Are you ready?** |
| **Checklist** |
| Please attach the following information: |  |
| * Company brochure
 | [ ]  |
| * Relevant product information/brochures/instructions for use
 |[ ]
| * Copies of any valid EC certificate according to MDD/IVDD
 |[ ]
| * Copies of any valid QMS certificate
 |[ ]
| * Organization chart of the headquarter as well as of subsidiaries/branches (if applicable)
 |[ ]
| * Copies of any valid QMS and regulatory certificates of the subcontractors
 |[ ]
| * Copies of existing EC certificate according to MDD/IVDD of OEMs (QM system as well as product-related approvals, if applicable)
 |[ ]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Place,** | **Date** |  | **Name**  |  | **Legally binding signature** |

Please send the completed questionnaire to the following contact address:

|  |  |
| --- | --- |
| ITC Zlíntřída Tomáše Bati 299CZ-764 21 ZlínCzech Republic  | Phone: +420-577-601254, -601269, -601266Fax: +420-577-104855e-mail: tzavisek@itczlin.czjbaluskova@itczlin.czmklinkovska@itczlin.cz  |

**Significant notes:**

1. **All the information in this questionnaire and all the delivered attached documents are considered to be confidential documents.**
2. **Completing this form does not mean that ITC is obliged to commence the conformity assessment procedure or issue any certificate.**
3. **If the corresponding conformity assessment procedure will not start for any reasons, ITC will either send the submitted information back to the potential client at his own cost or destroy the submitted information according to the potential client written demand.**
4. **Potential client is aware of the fact that conformity assessment process could start only if dully signed application form will be submitted to ITC in paper form (for download of the form, see** [**http://www.itczlin.cz/en/certification.product**](http://www.itczlin.cz/en/certification.product)**)**
5. **Potential client is aware of the fact that for issuing of the certificate(s) is necessary to sign the General framework agreement GFA (the GFA will be send on potential client demand, or it is available on the web address**[**http://www.itczlin.cz/en/certification-medical-devices-ce-itc**](http://www.itczlin.cz/en/certification-medical-devices-ce-itc)**). This GFA shall be signed and send to ITC together with duly filled and signed application.**

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| --- |
| **Area for comments and notices of ITC workers (please, do not fill)** |