**1. Manufacturer's company details and contact person (potential client)**

|  |  |
| --- | --- |
| **Company:** |  |
| SRN registration number: | (If assigned) |
| State: |  |
| Address: |  |
| Web: |  |

|  |  |
| --- | --- |
| **Statutory representative:**  |  |
| Phone: |  |
| E-mail: |  |

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

**2. Details of the company of the authorised representative (if any) and contact person**

|  |  |
| --- | --- |
| **Company:** |  |
| SRN registration number: | (If assigned) |
| State: |  |
| Address: |  |
| Web: |  |

|  |  |
| --- | --- |
| **Statutory representative:**  |  |
| Phone: |  |
| E-mail: |  |

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

**3. List of products and their classification**

|  |  |  |  |
| --- | --- | --- | --- |
| Products (+ intended use) | Sterile? | An invasive device? / period of use | ClassificationRisk class+ MDR Annex VIII rule +Product code (MDN / MDA / MDS) per Regulation2017/2185 |
|  | [ ]  yes \*[ ]  No | [ ]  Yes[ ]  No |  |
|  | Steam | ETO | Radiation | Other | Implant | Long term | Short term | Absorbable |  |
| 1 |  |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 2 |  |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 3 |  |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 4 |  |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| 5 |  |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]   |
| Have any of these products already been placed on the EU market under the previous Council Directive 93/42/EEC (MDD)? (“Legacy device”)If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| \* Is the sterilization process validated for the products? | [ ]  Yes [ ]  No |
| \* Is sterilization performed in your own production facility? | [ ]  Yes [ ]  No |
| Are the products manufactured in clean rooms?If so, what is the clean rooms classification (e.g. according to EN ISO 14644 series)? | [ ]  Yes [ ]  No |
|  |  |
| Do any of the products contain a medicinal substance (within the meaning of Directive 2001/83/EC) as an integral part?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Were non-living tissues or cells of human origin or derivatives thereof used in any of the products?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Were non-living tissues or cells of animal origin or derivatives thereof used in any of the products?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Does any of the products contain as an integral part an *in-vitro* diagnostic medical device (within the meaning of Regulation (EU) 2017/746?)If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Are any of the products also machinery (within the meaning of Directive 2006/42/EC)?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Do any of the products include nanomaterial or are they made of it? (For a definition of a nanomaterial, see chap. I, Article 2, point 18 of Regulation (EU) 2017/745)If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Do any of the products fall within the group of products without a medical purpose listed in Annex XVI to Regulation (EU) 2017/745?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Do any of the products contain carcinogens, mutagens, substances toxic for reproduction or endocrine disruptors listed in Annex I, point 10.4.1 of Regulation (EU) 2017/745?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Is any of the products a Class IIb active substance intended for the administration and/or disposal of a medicinal product as defined in Annex VIII, point 6.4 (Rule 12) of Regulation (EU) 2017/745?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Are any of the devices intended for use in combination with another medical device or product?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |
| Are any of the products a system or procedure set as defined in Article 2, points 10 and 11 of Regulation (EU) 2017/745?If yes, please specify which products are concerned (the item numbers above are sufficient): | [ ]  Yes [ ]  No |
|  |  |

*For further information on resource classification:* <https://ec.europa.eu/docsroom/documents/38670>

**4. Quality management system certificates**

|  |  |
| --- | --- |
| Does your company have a quality management system (QMS) certificate according to the requirements of EN ISO 13485 or EN ISO 9001?If yes, please indicate according to which of the above standards and its version (year of publication) is the QMS implemented? | [ ]  Yes [ ]  No |
|  |

*Please attach copies of existing QMS certificates.*

**5. Required conformity assessment procedure**

|  |
| --- |
| **MDR** - Regulation (EU) No 2017/745 |
| [ ]  Annex IX, chapter II[ ]  Annex IX, chapter I and III[ ]  Annex XI, Part A[ ]  Annex XI, Part A, Section 10 (only for Class IIa MD) |

|  |
| --- |
| **Any international approvals you hold:** |
| [ ]  US FDA[ ]  PAL GMP (Japan)[ ]  TCP Taiwan[ ]  other (please specify): |

*Please attach copies of existing approvals/certifications issued by authorities for non-European markets.*

|  |  |
| --- | --- |
| Has your application for conformity assessment of the above products according to MDR been submitted to another notified body in the past?If yes, please provide the name and identification number of the notified body. | [ ]  Yes [ ]  No |
|  |
| Has your application for conformity assessment of the above products according to MDR been rejected by a notified body (refusal to issue a certificate)?If yes, please give a brief justification.  | [ ]  Yes [ ]  No |
|  |
| Has your application for conformity assessment of the above products according to MDR been withdrawn by you?If yes, please give a brief justification.  | [ ]  Yes [ ]  No |
|  |

**6. Detailed information about your quality management system**

|  |  |  |  |
| --- | --- | --- | --- |
| **Please specify (approximately) the number of employees in each department of the company****Name and address of the company's head office and any subsidiaries or branches**  | **Department** | **Total** | Number of shifts |
| Quality control | Design and development | Purchase | Production | Warehouses | Sales | Services | Other |
|  |  |  |  |  |  |  |  |  |  |  |
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| **Please specify the subject matter (scope) of your quality system (QS) as stated in your quality manual:** |  |
| You use a consulting company for your QS implementation | [ ]  Yes, which one:[ ]  No |
| Do you use a consulting company in the field of technical documentation preparation? | [ ]  Yes, which one:[ ]  No |

|  |
| --- |
| **Please specify all relevant manufacturing technologies used for your product** |
| Joining technologies (special processes that require verification, e.g. welding, bonding and soldering) | [ ]  | Textile industry / fibre processing, weaving technology (bandages, wound dressings, implants) |[ ]
| Polymer processing (extrusion, injection moulding, dressing materials, etc.) |[ ]  Biotechnology (pharmaceuticals, reagents, etc.) |[ ]
| Metal (machining, grinding, cutting, finishing, etc.) |[ ]  Technology for ceramics production |[ ]
| Thin-film and thick-film technologies (electronic devices, e.g. for printed circuit boards, sensors and printed circuit boards) |[ ]  Precision Mechanics and Micromechanics (for precision products such as catheters, bone screws, optical devices etc.) |[ ]
| Chemical processing (preparation of solutions, gels, etc.) |[ ]  Technology requiring knowledge of pharmaceutical manufacturing |[ ]

|  |  |
| --- | --- |
| **Processes** | **Name and addresses of subcontractors who carry out the purchased processes**  |
| Design and development |  |
| Production  |  |
| Packaging |  |
| Sterilization |  |
| Warehouses |  |
| Services |  |

**7. Monitored manufacturing conditions for your products**

|  |  |  |
| --- | --- | --- |
| Is production carried out under controlled manufacturing conditions? | [ ]  Yes | [ ]  No |
| If so, which parameters or areas are controlled and monitored? |
| [ ]  Temperature[ ]  Humidity[ ]  Total number of particles[ ]  Microbiology | [ ]  ESD controlled rooms[ ]  Radiation protected rooms[ ]  Other: |

**8. List of necessary documentation accompanying the preliminary questionnaire**

|  |
| --- |
| **Please provide following additional information:**  |
|  |
| Number of technical documentation (TD) assembled for the products listed in section 3: |  |
| Specify which TD includes which products from section 3 (It is sufficient to provide the identification (number) of the TD with the assignment of the individual products (and, if applicable, their variants, models): |
| number (internal identification) of TD: | product name: | models: | basic UDI-DI |
|  |  |  |  |
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| **Please submit the following documents:***Note: The documents listed below are an essential part of the questionnaire submitted. Without these documents, the questionnaire cannot be considered valid.* |  |
| Detailed description of each product listed in section 3 |[ ]
| Instructions for use for each product listed in section 3 (Not required in exceptional cases for Class I and IIa devices - see MDR requirements) |[ ]
| Copies of all valid EU certificates issued in accordance with the MDD (93/42/EEC), if existing |[ ]
| Copies of all valid EU certificates issued in accordance with the MDR, if existing |[ ]
| Copies of valid QMS certificates (acc. to EN ISO 13485, alternatively EN ISO 9001), if existing |[ ]
| The organisational structure of the company's office as well as branches (if applicable) |[ ]
| Copies of all valid QMS certificates (EN ISO 13485, alternatively EN ISO 9001) held by critical process subcontractors |[ ]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date** |  | **Name of the company’s representative** |  | **Legally binding signature** |

**Please send the completed questionnaire to the contact address:**

|  |  |
| --- | --- |
| ITC ZlínBuilding 113Malotova 5264760 01 ZlínCzech Republic  | Phone: +420 572 779 954, - 953, - 955e-mail: mklinkovska@itczlin.cz jbaluskova@itczlin.cz tzavisek@itczlin.cz |

**Important messages for the potential client:**

1. **All information provided in this questionnaire and any attached documents are considered confidential by ITC and treated accordingly.**
2. **Completion of this questionnaire does not imply that ITC is obliged to initiate the procedure to issue a certificate.**
3. **If the conformity assessment procedure in question is not initiated for any reason, ITC will either return the information supplied to the potential client at the potential client's own expense or destroy the information if the potential client so requests.**
4. **The conformity assessment process can only begin if the prospective client has supplied a properly completed application on the ITC form
(see** [**https://medical-devices.itczlin.cz/en**](https://medical-devices.itczlin.cz/en)**).**
5. **One of the conditions for the issuance of the certificate(s) is the signing of the General Framework Agreement (referred to as the GFA-MDR, a sample of which is available on the ITC website** [**at**](http://www.itczlin.cz/cz/zdravotnicke-prostredky-ce) [**https://medical-devices.itczlin.cz/en**](https://medical-devices.itczlin.cz/en)**). The completed and signed GFA-MDR Agreement shall be sent by the Client to ITC together with a duly completed application form.**

|  |
| --- |
| **Space for comments and remarks by ITC staff (please do not fill in)****Questionnaire review date: ITC worker’s signature:** |