|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Legal Manufacturer Information** | | | | | | | | | | | |
| **Legal Entity Name** |  | | | | | | | | | | |
| **Registered HQ Address** |  | | | | | | | | | | |
| **Registered Production Address** |  | | | | | | | | | | |
| **Other Addresses** | **1.** | | | | | | | | | | |
| **2.** | | | | | | | | | | |
| **3.** | | | | | | | | | | |
| **Phone** |  | | | | **e-mail** |  | | | | | |
| **Web** |  | | | | **VAT Number** |  | | | | | |
| **No. of Employees** |  | | | | **No. of Shifts** |  | | | | | |
| **Registered Competent Authority** | |  | | | | **Single Registration No.** | | | | |  |
| **General Manager** | |  | | | | **e-mail** | |  | | | |
| **Management Rep.** | |  | | | | **e-mail** | |  | | | |
| **Responsible for Regulatory Compliance** | |  | | | | **e-mail** | |  | | | |
| **Affiliated organizaitons, if any** | |  | | | |  | |  | | | |
| 1. **Authorized Representative Information** *(if applicable)* | | | | | | | | | | | |
| **Legal Entity Name** |  | | | | | | | | | | |
| **Registered Address** |  | | | | | | | | | | |
| **Contact Person** |  | | **Phone** |  | | | **e-mail** | | |  | |
| **Competent Authority** |  | | | | **Registration Number (SRN)** | | | |  | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Requested Services** | | | | | | | | | | | | | | | | | | | |
| **EN ISO 13485:2016 QMS** | | | | | | | | | | | | | | | | | | | |
| Certification | | | Transfer | | | Scope Extension | | | | Recertification | | | | | | Others: | | | |
| **Requested ISO 13485 Scope** | | |  | | | | | | | | | | | | | | | | |
| **ISO 13485 excluded or not applicable clauses** | | |  | | | | | | | | | | | | | | | | |
| **EU 2017/745 Medical Device Regulations** | | | | | | | | | | | | | | | | | | | |
| Annex IX Conformity Assessment Based on a Quality Management System & Assessment of Technical Documentation | | | | | | | | | | | | | | | | | | | |
| Annex XI Part A, Production Quality Assurance\* | | | | | | | | | | | | | | | | | | | |
| Certification | | | Transfer | | | Scope Extension | | | | Recertification | | | | | | Others: | | | |
| **\* In case of requesting** **Production quality assurance certificate according to Annex XI, Part A, for class IIb and III devices, Annex X type examination certificate information** | | | | | | | | | | | | | | | | | | | |
| **Issuing NB:** | | |  | | | | | | **Certificate No.:** | | | | |  | | | | | |
| **Issue Date:** | | |  | | | | | | **Valid until:** | | | | |  | | | | | |
| **Certificate Scope:** | | |  | | | | | | | | | | | | | | | | |
| \*The certificate shall be provided along with the RFQ. | | | | | | | | | | | | | | | | | | | |
| 1. **Outsourced Processes, Suppliers & Subcontractors** | | | | | | | | | | | | | | | | | | | |
| **Outsourced Processes** | | | | Design & developement | | | | | | | | Production | | | | | | | |
| Sterilization | | | | | | | | Storage | | | | | | | |
| Other: | | | | | | | |  | | | | | | | |
| **Subcontractor/Critical Supplier Information** | | | | | | | | | | | | | | | | | | | |
| **#** | **Critical Supplier Name& Address** | | | | **Rendered Service** | | | | | | | | **Service Description** | | | | **No. of Employees** | | **QMS/MDR Certificate\*** |
| 1 |  | | | | Design & Development  Production  Partial Production Processes  Sterilization  Component  Other | | | | | | | |  | | | |  | |  |
| 2 |  | | | | Design & Development  Production  Partial Production Processes  Sterilization  Component  Other | | | | | | | |  | | | |  | |  |
| 3 |  | | | | Design & Development  Production  Partial Production Processes  Sterilization  Component  Other | | | | | | | |  | | | |  | |  |
| 4 |  | | | | Design & Development  Production  Partial Production Processes  Sterilization  Component  Other | | | | | | | |  | | | |  | |  |
| **\***Please attach a copy of the certificate held by subcontractor/supplier | | | | | | | | | | | | | | | | | | | |
| 1. **Documentation & Certificates** | | | | | | | | | | | | | | | | | | | |
| **QMS documentation completed?** | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | | | | No | | | | | | | | | | | |
| QMS Effective Date: | | | | | | | | Estimated Completion Date: | | | | | | | | | | | |
| Language of QMS documentation: | | | | | | | |  | | | | | | | | | | | |
| **Technical documentation completed?** | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | | | | No | | | | | | | | | | | |
| Technical Documentation Issue Date: | | | | | | | | Estimated Completion Date: | | | | | | | | | | | |
| **Current Certificates Status** | | | | | | | | | | | | | | | | | | | |
| The devices are already certified to MDR. | | | | | | | Notified Body: | | | |  | | | | Expiration Date: | | |  | |
| The devices are already certified to MDD. | | | | | | | Notified Body: | | | |  | | | | Expiration Date: | | |  | |
| The manufacturer is already certified to ISO 13485:2016. | | | | | | | Certification Body: | | | |  | | | | Expiration Date: | | |  | |
| Certification scope: | |  | | | | | | | | | | | | | | | | | |
| The manufacturer is already certified to a QMS standard. | | | | | | | Certification Body: | | | |  | | | | Expiration Date: | | |  | |
| Standard: | |  | | | | | | | | | Certificaion Scope: | | | |  | | | | |
| If suspended or withdrawn, please mention the reason. | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | |
| If the certificate is still valid, please write the reason for changing the notified/ certification body. | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | |
| 1. **Previous Applications** | | | | | | | | | | | | | | | | | | | |
| Have you lodged an application in parallel with another notified body for the same conformity assessment procedure? | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | | | | | | | No | | | | | | | | |
| Do you have an application refused by any notified body for the same conformity assessment you have lodged application? | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | | | | | | | No | | | | | | | | |
| If yes, please provide details: | | | | | | | | | | | | | | | | | | | |
| Have you withdrawn the application you have already submitted to another notified body prior to the decision of the notified body for the same conformity assessment you are applying for? | | | | | | | | | | | | | | | | | | | |
| If yes, please provide details: | | | | | | | | | | |  | | | | | | | | |
| 1. **Conflict of Interests** | | | | | | | | | | | | | | | | | | | |
| For devices and services given within this form, have you used or are you using a consultant to help you in your design, construction, marketing or maintenance of the products process or installation and maintenance of Quality Management System? | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | | | | | | | No | | | | | | | | |
| If yes, | | | | | | | | | | | | | | | | | | | |
| Consultant Name: | | | | | | | | | | | e-mail: | | | | | | | | |
| For devices and services given within this form, have you used Notice d.o.o services? (Excluding open trainings) | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | | | | | | | No | | | | | | | | |
| If yes, please provide details: | | | | | | | | | | | | | | | | | | | |
| Is there any connection/relationship between your organization and NOTICE testing subcontactors presented on www.notice.si? | | | | | | | | | | | | | | | | | | | |
| Yes | | | | | | | | | | | No | | | | | | | | |
| If yes, please provide details: | | | | | | | | | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Devices Information (fill this section for each product separately)** | | | | | | | | | | | | | | | | | | | | |
| Device Name |  | | | | | | | | | | | | | | | | | | | |
| Trade Mark |  | | | | | | | | | | | | | | | | | | | |
| Models/Variants |  | | | | | | | | | | | | | | | | | | | |
| Does it come in a set | Yes | | | | | | | | | No | | | | | | | | | | |
| Please define the contents of the set: | | | | | | | | | | | | | | | | | | | | |
| Intended use |  | | | | | | | | | | | | | | | | | | | |
| Mode of action |  | | | | | | | | | | | | | | | | | | | |
| EMDN Code |  | | | | | | MDA/MDN/MDS/MDT Code(s) | | | | | | | |  | | | | | |
| Class |  | | | | | | Classification Rule | | | | | | | |  | | | | | |
| Basic UDI-DI |  | | | | | | | | | | | | | | | | | | | |
| **Any clinical investigation conducted?** | | | | | No | | | | Yes (provide details) | | | | | | | | | | | |
| Health Institute Info |  | | | | | | | | Conducted Country | | | | |  | | | | | | |
| Reference of clinical investigation |  | | | | | | | | Completion date | | | | |  | | | | | | |
| **Critical Production Processes** | | | | | | | | | | | | | | | | | | | | |
| 1. | | | | | | | | | 4. | | | | | | | | | | | |
| 2. | | | | | | | | | 5. | | | | | | | | | | | |
| 3. | | | | | | | | | 6. | | | | | | | | | | | |
| **Materials Used in the Final Product** | | | | | | | | | | | | | | | | | | | | |
| 1. | | | | | | | | | 3. | | | | | | | | | | | |
| 2. | | | | | | | | | 4. | | | | | | | | | | | |
| **Sterilization Status** | | | | | Sterile  (indicate method) | | | To be sterilized prior to use (indicate method) | | | | | | | | Non-Sterile | | | | |
| ETO | Steam | | | | | | | | Radiation | | | | | Aseptic | | | | | | |
| Dry Heat | Hydrogen Peroxide | | | | | | | | Other: | | | | | | | | | | | |
| **Contact Status** | | | | Contact  (indicate contact type and duration) | | | | | | | | Non-contact | | | | | | | | |
| Central Nervous System (CNS) | | | | Skin | | | | | | | | Bone | | | | | | | | |
| Central Circulatory System (CCS) | | | | Dental | | | | | | | | Soft tissue | | | | | | | | |
| **Contact Duration** | | | | | | | | | | | | | | | | | | | | |
| < 1h | | | | | | 1h> <24h | | | | | | | > 24h | | | | | | | |
| 24h> <30d | | | | | | > 30d | | | | | | |  | | | | | | | |
| **Invasiveness** | | | | Invasive (indicate contact type) | | | | | | | | Non-invasive | | | | | | | | |
| Body Orifice | | | | | | | | | Surgically Invasive | | | | | | | | | | | |
| **Other specific device characteristics** | | | | | | | | | | | | | | | | | | | | |
| Incorporates medicine? | | | | | | | | | | | | | | | | | | Yes | | No |
| If yes, please name the substance: | | | | | | | | | | | | | | | | | | | | |
| Incorporates human blood/ human plasma? | | | | | | | | | | | | | | | | | | Yes | | No |
| Incorporates tissues or cells of human or animal origin, or their derivatives? | | | | | | | | | | | | | | | | | | Yes | | No |
| Incorporates or consists of nanomaterial? | | | | | | | | | | | | | | | | | | Yes | | No |
| Is the product composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body? | | | | | | | | | | | | | | | | | | Yes | | No |
| Does the product utilize biologically active coating? | | | | | | | | | | | | | | | | | | Yes | | No |
| Is the device intended to administer and/or remove a medicinal product? | | | | | | | | | | | | | | | | | | Yes | | No |
| Does the device incorporate software? | | | | | | | | | | | | | | | | | | Yes | | No |
| Does the software drive the device /influences the use of a device? | | | | | | | | | | | | | | | | | | Yes | | No |
| Measuring function? | | | | | | | | | | | | | | | | | | Yes | | No |
| Is there any vigilance reporting related to the product? | | | | | | | | | | | | | | | | | | Yes | | No |
| If yes, please provide details: | |  | | | | | | | | | | | | | | | | | | |
| Has there been any recall decision regarding your products? | | | | | | | | | | | | | | | | | | Yes | | No |
| If yes, please provide details: | |  | | | | | | | | | | | | | | | | | | |
| **Device tests** | | | | | | | | | | | | | | | | | | | | |
| Have the device tests been performed internally? | | | | | | | | | | | | | | | | | Yes | | No | |
| If no, please provide information of testing facilities | | | 1. | | | | | | | | 4. | | | | | | | | | |
| 2. | | | | | | | | 5. | | | | | | | | | |
| 3. | | | | | | | | 6. | | | | | | | | | |

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| --- | --- | --- | --- | --- |
| 1. **Documents to be submitted together with this form** | | | | |
| 1. Business License 2. Product IFU, Catalogue or other informational material 3. Previous CE & QMS Certificates 4. In case of requesting Production quality assurance certificate according to Annex XI, Part A, for class IIb and III devices, an EU type examination certificate according to Annex X 5. Latest balance sheet \* 6. Official document indicaitng the number of employees\* (Including (a) employees; (b) persons working for the enterprise being subordinated to it and deemed to be employees under national law; (c) owner-managers; (d) partners engaging in a regular activity in the enterprise and benefiting from financial advantages from the enterprise. Apprentices or students engaged in vocational training with an apprenticeship or vocational training contract are not included as staff. The duration of maternity or parental leaves is not counted.)   \* Submission of documents stipulated in 5 & 6 is optional. The information is requested in order to decide if the company falls into micro, small & medium size category to determine whether the related discount can be applied | | | | |
| 1. **Approval** (The correctness of the provided information is confirmed by the signer.) | | | | |
| **Authorized Person\*:** | |  | **Position:** |  |
| **Pertinent organization** | | Manufacturer Authorized Representative | | |
| **Date:** |  | | **Signature:** |  |
| \* The form shall be signed by an authorized signatory of the manufacturer or its EU representative. | | | | |