***Guidance on the use of this application form:***

* ***Use the TAB keys to jump between the typing fields.***
* ***Help topics are associated to most of the fields. When the field is selected double-click and help information is shown.***
* ***This application has 3 pages. Please fill in all relevant sections.***

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Company information:** | | | |
| Company name: |  | Phone: |  |
| Legal address (street & no.): |  | Fax: |  |
| Postal code & Town/City |  | PO Box no.: |  |
| Region/state: |  | Homepage: | www. |
| Country: |  | e-mail: |  |
| Contact person: |  | Shift system: |  |
| Position of contact person: |  |  |  |
| Date: | YYYY-MM-DD |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Sites related to the devices:** | | | | |
| ID | Name and address | Certificates (If any) | Emplo-  yees | Type of company and/or activity performed |
|  | The manufacturer, as specified above |  |  | Manufacturer |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
|  | Critical Suppliers |  |  |  |
| 6 |  |  |  |  |
| 7 |  |  |  |  |
| 8 |  |  |  |  |
|  | Special processes e.g. sterilization processes & type: | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | 1. **Product information (only relevant in relation to CE marking):** | | | | | |
| ID | Product name and description & GMDN Code | Intended use | See Note\*1 | Private  Label\*2 | Classification acc. annex IX of the MDD | |
| Class | Rule |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |

*\*1 Animal Tissue, medicinal products, Human Blood/plasma derivates*

*\*2 Also defined as: Own brand label*

| 1. **Route to CE mark (only relevant in relation to CE marking):** | | |
| --- | --- | --- |
| Device classes  (select relevant): | Assessment route applied for *(Annex XX)* | |
| Class Is |  | *Please note that class I devices which are not sterile or have a measuring function do not require Notified Body approval.* |
| Class Im |  |  |
| Class IIa |  |  |
| Class IIb |  |  |
| Class III |  |  |
| Sterile Procedure Pack |  |  |

|  |  |  |
| --- | --- | --- |
| 1. **Expected date for submission of documentation and audit:** | | |
| Documentation | Date: | Notes |
| Copy of the Quality system to DGM | YYYY-MM-DD |  |
| Technical documentation | YYYY-MM-DD |  |
| Certification audit | YYYY-MM-DD |  |

|  |  |  |
| --- | --- | --- |
| 1. **Only relevant for annex IV Certifications/Lot verification:** | | |
| Question: | Answer / Notes | Notes |
| Requested verification Method |  |  |
| Lot/Batch or Serial Number identification of products |  |  |
| Batch identification |  |  |
| Batch Size (Pcs) |  |  |
| Production testing acc. to which standards: |  |  |

|  |  |
| --- | --- |
| 1. **General questions and requirements with respect to quality system certification**   **(only relevant if quality system certification is requested):** | |
| Certification to which standard(s) | Proposed scope |
|  |  |
|  |  |
|  |  |
|  |  |
| Description of the products and product categories: |  |

|  |  |
| --- | --- |
| 1. **General information:** | |
| Number of audits per year |  |
| Language of communication with Presafe |  |
| Language of Quality Manual |  |
| Language of technical documentation |  |

|  |
| --- |
| 1. **Notes & additional information:** |
| Specify: |

Please send the completed questionnaire by e-mail to:

**Presafe Denmark A/S**

**Tuborg Parkvej 8**

**2900 Hellerup**

**Denmark**

**Phone: +45 3945 4999**

**Email: presafedk@presafe.com**