***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 | PrivateLabel\*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 |  |  |

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| 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 |       |

|  |
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| 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**