***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: |       |
| City/town & postal code |             | PO Box no.: |       |
| Region/state: |       | Homepage: | www. |
| Country: |       | e-mail: |       |
| Contact person: |       | Shift system: |  |
| Position of contact person: |       | Date: | YYYY-MM-DD |

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| 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 |       |       |       |  |

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| 1. **Product information (only relevant in relation to CE marking):**
 |
| ID | Product name and description | Intended use  | PrivateLabel\* | Annex II list A, Annex II list B or self-testing |
|
| 1 |       |       | [ ]  |  |
| 2 |       |       | [ ]  |  |
| 3 |       |       | [ ]  |  |
| 4 |       |       | [ ]  |  |

*\* Also defined as: Own brand label*

| 1. **Route to CE mark (only relevant in relation to CE marking):**
 |
| --- |
| Product category (select relevant): | Assessment route applied for *(Annex XX)* |
| Annex II, List A |  |
| Annex II, List B |  |
| Devices for self-testing |  |

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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. **IVD batch verification (only relevant for CE marking according to Annex VI):**
 |
| Question: | Answer / Notes | Notes |
| Requested verification Method |  |       |
| Batch Identification |       |       |
| Batch Size (Pcs) |       |       |

|  |
| --- |
| 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: |       |

|  |
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| 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**