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| **Company** |
| Company name and address: |                      |
| Company file number: | 70XXX    |

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| Type of change*(Please tick off all the appropriate tick-boxes relevant for the change)* |
| Product related |  |
| [ ]  | New or change of intended use, indications or the ability to fulfil the intended use/indications (Not relevant for devices in class Im and Is) | [ ]  | ALL device changes and ALL process changes that impacts or can impact compliance (only for device covered by Type examination or Design examination) |
| [ ]  | Change of clinical data (all changes for Class III and significant changes for class IIa, IIb) | [ ]  | Significant change of patient contact materials (implantable devices only) |
| [ ]  | Termination or change to agreed PMCF plan (all classes) | [ ]  | Implementation of Electronic instruction for use (regulation 207/2012) (all classes) |
| [ ]  | Significant changes to the risk analysis, the risk controls implemented or the risks of the device. (all classes) | [ ]  | Request for addition of:* a IIb device, in a new GMDN code, to the certificate, and/or
* a IIa device, in a new MD code, to the certificate
 |
| [ ]  | Significant changes in the compliance to the essential requirements (E.g. change in the used standards, not (fully) using harmonized standards, device used with other accessories/systems/devices)(all classes) | [ ]  | Change of product identifier/type number (all classes) Addition or removal of device(s) to the product list. (all classes) |
| [ ]  | Change of technology (all classes) | [ ]  | Other, Specify:      |
| **Quality system related** |  |  |
| [ ]  | Change of contact person  | [ ]  | Change of Authorized Representative |
| [ ]  | Move of facilities and/or significant move of process (e.g. Manufacturing in a new facility) | [ ]  | Additional facility to be added to the certificate |
| [ ]  | Change of legal entity, company name or ownership. | [ ]  | Change of scope, product families or product groups on certificate(s) |
| [ ]  | Significant change to one or more processes (e.g. Design process, supplier control process, CAPA process, manufacturing process) or controls (Test/inspection, traceability…)  | [ ]  | Management or organization changes that can impact the operation of the quality system (e.g. Management change/ change of key personnel (QA manager, RA manager)/ change in quality responsibilities/ organization change) |
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| [ ]  | Significant change of compliance to standards relevant for the system! (e.g. EN ISO 11607-1, EN ISO 11137-1, EN ISO 13408-1, EN ISO 13485) | [ ]  | Any change or process related to medical substances, human blood derived products, animal tissue or Nano materials |
| [ ]  | Significant change of Quality manual | [ ]  | Addition or change of a special process that may significantly cover the compliance of the device(s) |
| [ ]  | New or significant change to an process control system or Quality system control system (e.g. electronic archiving system, electronic signatures, ERP system, electronic quality system  | [ ]  | New or significantly changes to: sterilization process, sterilization validation, production environment, environment/ bioburden control and monitoring system, Endotoxin controls, new or changed sterilization supplier/chamber. |
| [ ]  | New significant subcontractor/supplier or change of controls for a significant subcontractor/supplier | [ ]  | Subcontracting of quality system elements (e.g. purchase, PMS/PMCF, clinical trial conduction, sales and marketing) |
| [ ]  | Significantly change of production technology | [ ]  | Other, Specify:      |
| .Signature*(contact person)*  |
|       |  |       |
| *Place*  |  | *Date* |
|  |  |  |
|  |  |
|   |
| ***Signature*** *and printed name* |

*Change notifications are to be send to Presafe Denmark A/S*

*Email:* *presafedk@presafe.com* *or
Mail: Tuborg Parkvej 8, DK 2900 Hellerup, Denmark*

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| **Description of the change***A brief description of the modifications compared to the approved design/device or the approved quality system - If relevant include the reason for the change and justify the reason for the change being insignificant* |
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| **New or revised products***Please specify: Intended use of the device, the classification of the device and the classification rule used* |
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| MDD Specific | Class: |  |  According to rule: |  |
| IVD Specific | Category: |  |  |
| All devices | GMDN Code |       | *Please see* [*www.gmdnagency.com*](http://www.gmdnagency.com) |
| All devices | MD/IVD/MDS code(s) |       | *Please see NBOG F 2012-1 and F 2012-3 (nbog.eu)* |
| Medicinal product, Animal tissue product or human blood/plasma derivate incorporated: |  |
| I, The applicant, hereby declare that no application has been lodged with any other notified body than Presafe Denmark A/S for the same product-related quality system and the same type/product. |

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| **Documentation included***Please specify the documentation, which is enclosed to this change notification* |
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| **Presafe evaluation** |
| Sample plan impact: |
| Assessment result:  |
| Init. sign. and date: |