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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* |
|  | |  | | |  |
|  | | | | |  |
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| ***Signature*** *and printed name* | | | | | |

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

*Email:* [*presafedk@presafe.com*](mailto: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: |