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| **Applicant** | |
| Company name and address: |  |
| Client file number: |  |

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| Type of change *(Please tick off all the appropriate tick-boxes relevant for the change)* | | | | | |
| Product related | | | Quality system related | | |
|  | Change of intended use or the ability to fulfil the intended use | |  | Change of legal entity or company name. | |
|  | Change of clinical data | |  | Move of facilities | |
|  | Significant changes to the risk analysis or the risk involved when using the device | |  | Change of contact person | |
|  | Significant changes in the compliance to the essential requirements | |  | Management change/ change in quality responsibility/ organization change | |
|  | Significant change of performance data | |  | Change of Authorized Representative | |
|  | Change of a safety-related function(s) | |  | Significant change to production process | |
|  | Change of technology (no other changes) | |  | Change of production technology | |
|  | Significant change of user information (Manual/leaflet, labelling or embedded). | |  | Change of special process (soldering, sterilization or similar) | |
|  | Change of Materials (Patient contact) | |  | Revised testing activities | |
|  | Change of product identifier/type number | |  | Post market surveillance | |
|  | Addition of product to certificate / product list | |  | Quality manual/procedures | |
|  | Removal of product from certificate / product list | |  | New subcontractor | |
|  | Significant change of human interface | |  | Change of scope | |
|  | Significant change/addition of accessories or other devices to be connected/used with the device | |  | Subcontracting of quality system elements (e.g. purchase, PMS, sales and marketing) | |
|  | Other, Specify: | |  | Other, Specify: | |
| Signature  *(contact person)* | | | | | |
|  | |  | | |  |
| *Place* | |  | | | *Date* |
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|  | | | | | |
| *Signature and printed name* | | | | | |

*Please note:*

* *The Change notification must be signed!*
* *Notified Body recommendation 2.5.2/Rec.2: “Reporting of design changes and changes of the quality system” provides further information. The recommendation is available on:* <http://ec.europa.eu/health/medical-devices/index_en.htm>

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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* | | |
| All devices | MD code |  | *Please see NBOG BPG 2009-03 (www.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: |