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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* |
|  |  |  |
|  |  |
|   |
| *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: |