Design Change Record and Evaluation Form

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| **Requestor: GJGD** | | | | **Date:** Click here to enter a date. | | | | |
| **Plan of change approved by: GJGD** | | | | **Date:** Click here to enter a date. | | | | |
| **Change form Number:** CF-Click here to enter text. | | | | | | | | |
| **Change Applies to:**  **VISI** | | | | | | | | |
| **Design input references:**  Click here to enter text. | | | | | | | | |
| **Action plan summary:**  Click here to enter text. | | | | | | | | |
| **Description of change:**  Click here to enter text. | | | | | | | | |
| **Benefits of change:**  Click here to enter text. | | | | | | | | |
| **Document references ie drawings:** | | | | | | | | |
| **To meet ISO 13485:2016 7.3.9, determine significance of change to:** | | | | | | | | |
| function | Click here to enter text. | | | | | | | |
| performance | Click here to enter text. | | | | | | | |
| usability | Click here to enter text. | | | | | | | |
| Safety and regulatory requirements | Click here to enter text. | | | | | | | |
| **Product changes should be considered substantial if the change may affect:** | | | | | | | | |
| The conformity with the essential requirements / general safety and performance requirements / safety and effectiveness requirements | | | | | Yes, substantial | | | |
| The indications and/or contraindications and/or warnings determined by the manufacturer to be appropriate to ensure the clinical performance of the device | | | | | Yes, substantial | | | |
| **When determining whether or not a particular product change is “substantial” following considerations should be made (the list is not exhaustive):** | | | | | | | | |
| Changes of the intended purpose and/or the performance specification of the device? | | | | | | | Yes  NA | Yes, substantial |
| Changes of the materials of the device? Are biocompatibility / compliance with ISO 10993-1 affected? | | | | | | | Yes  NA | Yes, substantial |
| Changes to a Bill of Materials (BOM)? Is a new part, update of an existing part, or withdrawal of a part involved.? | | | | | | | Yes  NA | Yes, substantial |
| Is a new Basic UDI-DI required? | | | | | | | Yes  NA | Yes, substantial |
| Compliance with product standards (IEC 60601-1, IEC 60601-1-2 etc.) or common specifications? | | | | | | | Yes  NA | Yes, substantial |
| Are significant changes to the assembly, in-process or final testing required? | | | | | | | Yes  NA | Yes, substantial |
| Changes to packaging specifications / configuration? Is Packaging Integrity / Transport Testing affected? | | | | | | | Yes  NA | Yes, substantial |
| Changes to product labelling and/or brochures, guides or website? New or revised product labels / user manuals, add / remove symbols, claims, indications for use, contraindications, precautions / warnings? | | | | | | | Yes  NA | Yes, substantial |
| Changes of suppliers / sub-contractors and existing agreements and / or purchase orders? | | | | | | | Yes  NA | Yes, substantial |
| Are new hazards introduced which have not previously been addressed? | | | | | | | Yes  NA | Yes, substantial |
| Are risks associated with existing hazards affected? | | | | | | | Yes  NA | Yes, substantial |
| Are changes to software specifications required? Do they affect compliance with IEC 62304? | | | | | | | Yes  NA | Yes, substantial |
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| Does the change trigger a need to alter the indications or contraindications for use or warnings necessary to ensure safety and efficacy for the intended use of the device? | | | | | | | Yes  NA | Yes, substantial |
| Does the change mean that the device will have different end users or be used in a different manner? | | | | | | | Yes  NA | Yes, substantial |
| Does the change mean that the clinical data/performance evaluation data for the original device is not sufficient to assure conformity of the changed device with the required characteristics and performance? | | | | | | | Yes  NA | Yes, substantial |
| Is the change a direct result of actions taken related to concerns arising from Post Market Surveillance including incidents/recalls/complaints? | | | | | | | Yes  NA | Yes, substantial |
| Is the change driven by the development of the state of the art? | | | | | | | Yes  NA | Yes, substantial |
| Does the change relating to a manufacturing process, facility or equipment impact the product´s safety or performance? | | | | | | | Yes  NA | Yes, substantial |
|  | | | | | | |  |  |
| Does the change have any effect on existing devices in customers’ hands? If yes, complete following two items; otherwise mark this and following two items NA | | | | | | | Yes  NA | Yes, substantial |
| Should the change be notified to customers with existing devices? If yes, evidence of notification. If no, justification.  Click here to enter text. | | | | | | | Yes  NA | Yes, substantial |
| Will there be any need to recall existing devices? If yes, evidence of recall; if no, justification with risk analysis.  Click here to enter text. | | | | | | | Yes  NA | Yes, substantial |
| **If ‘substantial’ to any of the above, notify Regulatory Bodies and other entities tha should be notified according to SSI-SOP-8.**  **Date of notification:** Click here to enter a date.**or**  **N/A** | | | | | | | | |
| **Regulatory Body** | | **Potential Actions** | **Preapproval required** | | | **Notes** | | |
| Notified Body (NB) | | NB Notification. Use Form SSI-QF-18A | Yes  No  NA | | |  | | |
| UK Approved Body (UKAB) | | UKAB Notification. Use Form XX (TBC) | Yes  No  NA | | |  | | |
| FDA | | FDA Notification  510 (K) Update  FDA Annual Report  Registration and Listing Database | Yes  No  NA | | |  | | |
| Health Canada (HC) | | HC Notification  License Amendment  HC Annual Report | Yes  No  NA | | |  | | |
| Notify any economic operators (importers, distributors, EU Authorized Representative)? Change to agreements with economic operators required? | | | | | | | | |
| Yes, list parties to notify and details of notification: | | | Yes, list agreements to be updated: | | | | | |
| Are changes to product registrations in the relevant national or international databases required?. Consult SSI-SOP-23, SSI-SOP-26 and indicate below all that apply, as required. | | | | | | | | |
| EUDAMED | | MHRA | Other, please specify: | | | | | |
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| **Verification document(s) reference #:**  **-** | | | | | | | | |
| **Validation document(s) reference # (if applicable):**  **-** | | | | | | | | |
| **Update to existing regulatory documentation (if applicable):**  Technical Documentation  Strategy for Regulatory Compliance  Other, please specify: | | | | | | | | |
| **Changes reviewed by CEO** including for any changed or additional risks and their effect on constituent parts and product in process or already delivered Click here to enter a date. | | | | | | | | |
| **Approval by CEO** Click here to enter a date. | | | | | | | | |
| **Change made?** Yes NA | | | | | | | | |