MDR Notification of Product Changes

Please use this form to get approval from SGS prior to any significant changes to a certified Medical Device

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| --- | --- | --- | --- | --- | --- | --- |
| Client Name: |  | | | Date: |  | |
| Client SRN: |  | | | | | |
| Device name: |  | | Basic UDI-DI: | | |  |
| All SGS Certificate Number(s) affected by the change: | |  | | | | |
| Contact name: |  | | | | | |
| Contact Tel: |  | | | E mail: |  | |

### Nature of Change (Changes should include additions and deletions)

|  |  |  |  |
| --- | --- | --- | --- |
| Please tick all relevant categories of change3 | | | |
| Implementing a *corrective action4*  (Defined in MDR (EU) 2017/745 Article 2 (67)) |  | Implementing a *field safety corrective action4,5*  (Defined in MDR (EU) 2017/745 Article 2 (68)) |  |
| New medical device, system or procedure pack |  | Materials | ☐ |
| Name, trade name or other identification of the device, device version, variant, or model1, 3, 4 | ☐ | New UDI-DI1 | ☐ |
| Intended use | ☐ | Safety feature or function | ☐ |
| Labelling or Instructions for use | ☐ | Accessories or Compatibility with other Devices | ☐ |
| Device Performance or Conformance with standards | ☐ | New clinical evidence or update to CER, PSUR or SSCP2 | ☐ |
| Software version1, 3, 4, 6 | ☐ | Device risk analysis, risk classification | ☐ |
| Software performance, interpretation of data | ☐ | Software algorithms, database structures, operating platform, architecture, user interfaces or channels for interoperability | ☐ |
| New supplier or changes in the existing | ☐ | Change to the audited facility or related infrastructure | ☐ |
| Change to the contact person or PRRC | ☐ | Other significant staff change | ☐ |
| New critical subcontractor or changes in the existing | ☐ | OEM arrangement | ☐ |
| Production technology or production process | ☐ | Other | ☐ |
| Note 1: According to MDCG 2018-1, “a new UDI—DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability. In particular, a new UDI-DI shall be required in the case of any change of the following elements: name or trade name, device version or model, labelled as single use, packaged sterile, need for sterilization before use, quantity of devices provided in a package, critical warnings or contra-indications (e.g. containing latex or DEHP), CMR/Endocrine disruptors, colour, language.”. In addition, according to Annex VI Part C section 6.5.2 A new UDI-DI shall be required for DEVICE SOFTWARE if modifications include “new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability”.  Note 2: Guidance for PSUR and SSCP is given in MDCG 2019-9.  Note 3: According to MDR (EU) 2017/745 Article 120 (3) significant changes to the certified MDD 93/42/EEC products are not allowed during the MDR transition period. For the assessment of significance, the guidelines in MDCG 2020-3 shall be considered.  Note 4: According to MDR (EU) 2017/745 Article 83 (4), if you implement corrective actions or field corrective actions you should notify the Competent Authority (CA) and the NB. This applies also to the certified MDD 93/42/EEC products during the MDR transition period. SGS expects to receive the notifications prior to implementing the corrective action. The CA’s may have other and varying timelines; follow the reporting timeline instruction of your own CA. Please send a copy or summary of your communication with the CA to SGS.  Note 5: Where a serious incident is identified or a field safety corrective action is implemented, it shall be reported in accordance with Article 87. Please also send the vigilance form FPMDREG2003 to SGS Fimko.  Note 6: Software certification is based on the software version (e.g. 2.0) indicated either in the certificate and/or in the technical documentation assessment report. Non-significant updates to the software such as minor bug fixes need to be implicated in the software version identifier (e.g. 2.0.2). It is generally assumed that changes to the second digit (e.g. 2.0 🡪 2.1) imply changes that are significant and should be notified to and approved by the NB. If the identification of the software follows some other scheme, the manufacturer should clarify the meaning of the SW version digits in the change notification. | | | |

### Reason for change

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### Details of Change [attach additional documents if required]

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Significance of Change

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| Was the risk analysis revised? If YES, please tick | ☐ |
| If NO, please give the reason why the existing risk analysis still applies: | |
|  | |
| Please state whether the clinical evaluation or performance evaluation has been revised. If YES, please tick | ☐ |
| If NO, please give the justification why the clinical evaluation / performance evaluation was not revised: | |
|  | |

### Review of Notification by SGS Fimko’s or its affiliate’s receiving person (Lead Auditor or Product Assessor)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Administrative change: <justify> | | | | ☐ |
| Low risk change: <justify> | | | | ☐ |
| High risk or unclear change: <justify> | | | | ☐ |
| <SGS receiver’s other review notes and conclusions> | | | | ☐ |
|  | | | | ☐ |
| Other action: | | | | ☐ |
| Comments: | | | | |
|  | | | | |
| Reviewed by: |  | Date: |  | |

### Review of Notification by SGS Fimko (Final Reviewer or Certification Decision Maker)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Change can’t be implemented: <justification>** | | | | ☐ |
| 1. **Change can be implemented if the following actions and/or comments have been addressed** | | | | ☐ |
| No action required | | | | ☐ |
| Schedule for review by QMS auditor at the next scheduled visit | | | | ☐ |
| Proposal for certificate change by an addendum letter only (administrative change) | | | | ☐ |
| Proposal for certificate change with the update of the technical documentation sampling plan and schedule to include the assessment of change (low risk change) | | | | ☐ |
| Proposal for certificate change only after the completion of a successful technical documentation assessment (high risk change) | | | | ☐ |
| Other action: | | | | ☐ |
| Comments: | | | | |
|  | | | | |
| Reviewed by: |  | Date: |  | |

### Approval of the reviewers’ conclusions by SGS Fimko (Certification Decision Maker or NBM)

|  |  |  |  |
| --- | --- | --- | --- |
| Approved by: |  | Date: |  |