|  |
| --- |
| **Please send this (Significant) Change Notification ((S)CN) to your responsible TÜV Rheinland Office from the dropdown menu:** Use this dropdown to select your point of contact |
| Company name |  |
|  |  |
| Company address*Multi-site Organizations: Include affected site if applicable* |  |
|  |  |
| Contact name & email |  |
|  |  |
| Submission date of (S)CN |  |
|  |  |
| If applicable, estimated date of planned implementation of the (S)CN |  |
|  |  |
| Is the change to your QMS and/or to a product?  | QMS [ ] Product [ ]  | Both (please add reasoning) |
|  |
|  | Neither (please add reasoning) |
|  |  |
|  |  |
| Certificate(s) affected by change |  |
|  |  |
| If the change is on an MDD/IVD certified device that has not yet transitioned to MDR/IVDR | [ ] Confirmed not significant per MDR Article 120 / IVDR Article 110 / MDCG 2020-3 (MDR) / MDCG 2022-6 (IVDR) (add justification on next page) |
|  |  |
|  |  |
| Is the change on a device that has already transitioned to MDR/IVDR? | [ ]  Change is on MDR certified device[ ]  Change is on IVDR certified device |
|  |  |
| Is the change on a device that has already transitioned to UK MDR? | [ ]  Change is on UK MDR certified device (MDD-based)[ ]  Change is on UK MDR certified device (IVDD-based) |

# Description of the Change

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|  |

# Attachments to this (S)CN

|  |  |
| --- | --- |
| [ ]  New Application(s) / contract | [ ]  MDCG Justification |
| [ ]  Declaration of Conformity  | [ ]  Certificates of the Sterilization Facility |
| [ ]  New / Revised Technical Documentation | [ ]  Risk Analysis |
| [ ]  EMF Certificates, QS certificates, certificates issued by a Notified Body/UK Approved Body | [ ]  Essential Requirements / General Safety and Performance Checklist |
| [ ]  Others:  |  |
| The following documents will be submitted later (include estimated date of submission): |
|  |

# Following Sections to be filled in by TÜV Rheinland

## Expert Evaluation of the (S)CN

|  |  |
| --- | --- |
| Expert(s) Name & Date: |  |
| A | [ ]  Change(s) proposed by the company can be ACCEPTED. No further activities by TÜV Rheinland are needed. |
| B | [ ]  Change(s) proposed by the company can be ACCEPTED. However further activities are needed for final evaluation, suggested as follows:* List further activities (incl. planned effort)
 |
| C | [ ]  Change(s) proposed by the company CANNOT BE ACCEPTED. Justification: Enter text here |

## Certifier Evaluation of the (S)CN

|  |  |
| --- | --- |
| Certifier(s) Name & Date: |  |
| A | [ ]  Evaluation by the expert can be FOLLOWED AND IS APPROVED. The changes requested by the company are accepted as proposed with no further actions. |
| B | [ ]  Evaluation by the expert can be FOLLOWED AND THE PROPOSED ACTIONS ARE APPROPRIATE. The proposed activities must be completed before the change(s) is fully accepted.[ ]  Evaluation by the expert CANNOT BE FULLY ACCEPTED AS PROPOSED. Following additional or changed activities are necessary to fully accept the change(s):* List further activities (e.g. Evaluation Report)
 |
| C | [ ]  Rejection of the change by the expert is correct, the change(s) CANNOT BE ACCEPTED AND IS REJECTED. |
| Certifier Signature: |  |

## Closure of the (S)CN (For Case B)

|  |  |
| --- | --- |
| Certifier(s) Name & Date: |  |
| All activities required by this change are **COMPLETED AND ACCEPTED**, including audits, technical documentation assessments and updates to related documents. The change request is closed. |
| Certifier Signature: |  |