(Significant) Change Notification

TÜVRheinland®

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)

Note 1: Upon submission of this (S)CN, a quotation with the estimated effort for processing the initial evaluation will be created. Further activities to evaluate the proposed actions will be charged separately.
Note 2: Only one change will be accepted per (S)CN. Multiple changes in one form will result in additional charges.
Note 3: TÜV Rheinland does not differ between significant or substantial change terminology. For guidance related to substantial changes, refer to MDR 2017/745, IVDR 2017/746, UK MDR 2002 & NBOG BPG 2014-3.
For significant changes refer to MDR 2017/745 Article 120 / MDCG 2020-3 & IVDR 2017/746 Article 110 / MDCG 2022-6.
Note 4: Even if it may not be considered a significant change, the certification body (TRLP, TRUK, TRNA) must be informed of ANY change in the product scope that is in scope of EC Directive, EU Regulation and UK MDR certifications.

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Description of the Change

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):	

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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. Following internal documents have been updated: ____ Comments (if 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

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. Enter text here if needed
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(s) Name, Date & Signature: