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| **TÜV Rheinland Certification Body** | **TÜV Rheinland LGA Products GmbH**  **TUV Rheinland UK Ltd.**  **TÜV Rheinland of North America Inc.** |
| Please provide the (Significant) Change Notification to your responsible TUV Rheinland Office:  Germany: Medical-Auditsupport@de.tuv.com  Europe: SCN-medical-EUR@tuv.com  France: Client representative; Medical.fr@tuv.com  North America: ChangeNotice@us.tuv.com  Asia Pacific: Client representative  Greater China: Sales representative  EMEA: Sales representative | |
| **Company name:** |  |
| **Company address:** |  |
| **Contact person:** |  |
| **Submission date of this (Significant) Change Notification:** |  |
| Please be informed that, upon submission of this (Significant) Change Notification, you accept a basic charge of 4 hours for an initial evaluation. Multiple changes in one notification may result in additional costs. If further activities to evaluate the proposed actions are needed, a quotation will be provided. | |
| **Affected TÜV Rheinland QMS certificates (EN ISO 13485, MDD, IVDD, MDR, IVDR, UK MDR, MDSAP)**  **(HD, DD, ED, HL, HI,  HZ, DZ, HX, DX, SX, HQ, DQ, EQ, HA, DA, SQ, MD certificates):** |  |
| **Estimated submission date of additional documents (if not yet provided with this Notification):** |  |

Nomenclature: “significant change” and “substantial change” may be used interchangeably.

For requirements and guidance related to significant changes please refer to MDR 2017/745, IVDR 2017/746, UK MDR 2002 and NBOG BPG 2014-3.

**Remark**

Even if it may not be considered a significant change, the certification body (TRLP, TRUK) 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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| **Mandatory information for notifications under MDD/IVDD**  Please note that significant changes as per EU Regulation 2017/745 (MDR) Article 120(3) / EU Regulation 2017/746 (IVDR) Article 110(3) cannot be processed under MDD/IVDD anymore.  Please provide your justification following the flowchart in [MDCG 2020-3](https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_guidance_significant_changes_annexes_en.pdf) (MDR) or [MDCG 2022-6](https://ec.europa.eu/health/document/download/14c2d8dd-8489-4db5-b035-1c174f17fb54_en?filename=mdcg_2022-6.pdf) (IVDR) to show that the change is not considered a corresponding significant change.  **See following justification/document:** Enter text here   * If the evaluation by TÜV Rheinland identifies a corresponding significant change, it will NOT be accepted and all incurred costs will be invoiced. |

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| New Company or Legal Entity name and/or address |
| New products NOT yet covered by approved device subcategories (UK MDR class IIa/ Annex II, List B) or device categories (MDR class IIa/ IVDR class B),  or generic device group as categorized by different GMDN/EMDN codes (UK MDR/MDR: class IIb / IVDR: class C) |
| New product or product name (change in Product List and Application / IVDD: Product Description Form) |
| Change of design facilities or manufacturing facilities |
| New External Manufacturing Facility (EMF) or critical supplier |
| Change in quality system (e.g. significant reorganizations, or changes in QMS structure) |
| Change of authorized European representative / UK Responsible Person |
| Change in core processes like design process, manufacturing, inspection or PMS/PCF/PMPF process |
| Change of special processes (e.g. sterilization processes or facilities) |
| Others (please specify):  Enter text here |

**Remark**

Depending on the nature of the change, on-site audit(s) or documentation assessment(s) may be required.

**Brief description of the changes**

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| Enter text here |

**Note**

For product additions or changed production related facilities, the attachment of the TÜV Rheinland forms “**Product List and Application**” (MDR: MS-0030360 / IVDR: MS-0034326 / UK MDR: MS-0045276) or “**Product Description Form IVDD/UK MDR**” (MS-0023783) is required.

For MDD, no revised “Product List and Application” (MS-0023786) is acceptable after 26 May 2021. Please provide “**Request for update of MDD certification scope**” (MS-0045432) instead.

For IVDD, no revised “Application for EC Conformity Assessment Procedure (QM system IVD)” (MS-0023798) is acceptable after 26 May 2022. Please provide “**Product Description Form IVDD/UK MDR**” (MS-0023783) instead.

**Additional documents attached** (in order to verify the nature of the submitted change notification)**:**

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| New Application (s)/new contract | Certificates of the sterilization facility |
| Declaration of Conformity | EMF Certificates, QS certificates,  Approvals issued by a Notified Body |
| New/revised technical documentation | Essential Requirements /  General Safety and Performance checklist |
| Risk Analysis | Others:  Enter text here |

**To be filled in by TÜV Rheinland:**

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| **Evaluation of the notification** | | |
| Evaluation by expert(s): Name(s) + date | | TÜV Rheinland LGA Products GmbH  TUV Rheinland UK Ltd.  TÜV Rheinland of North America Inc. |
| A | The action(s) proposed by the company **can be followed**. No further activities by TÜV Rheinland are needed and the implementation of the action(s) should be accepted. | |
| B | The action(s) proposed by the company **can be followed**. For a final evaluation further activities are suggested as follows:   * Evaluation Report * List further activities (incl. planned effort) | |
| C | The action(s) proposed by the company **cannot** **be followed**.  Justification: | |

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| Evaluation by certifier: Name | | | TÜV Rheinland LGA Products GmbH  TUV Rheinland UK Ltd.  TÜV Rheinland of North America Inc. |
| A | The evaluation by the expert **can be followed and is approved**. The actions of the company are accepted as proposed. | | |
| B | The evaluation by the expert can be followed and the proposed actions are approved. The activities shall be performed like suggested. | | |
| C | The evaluation by the expert **cannot (completely) be followed**. Following additional actions are needed:   * List further activities (e.g. Evaluation Report) | | |
| D | The rejection of the (significant) change by the expert is confirmed by the certifier. | | |
| Certifier Digital Signature | |  | |