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| **TÜV Rheinland**  **Certification Body** | **TÜV Rheinland LGA Products GmbH**  **TUV Rheinland UK Ltd.** |
| Please provide the (Significant) Change Notification (Product Assessment) 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  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. | |
| **TÜV Rheinland EC Design-Examination certificate number (MDD/IVDD/AIMDD/UK MDR)**  **(ID, IL, II, IA, IQ certificates):** |  |
| **TÜV Rheinland technical documentation assessment certificate number (MDR/IVDR)**  **(IZ, IX 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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| **Product related change:**  **Applies to all significant changes to approved EC Design-examination applications according to MDD/IVDD/AIMDD/UK MDR:**  **MDR/IVDR: Technical Documentation Assessment according to Annex IX, chapter II** |

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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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| **Device related changes, that could affect the safety and performance of the device or the conditions prescribed for use of the device, such as:** | |
| Change in device-range covered, additional model(s) | Change of intended use (e.g. claims, indications, contra-indications, warnings) |
| Addition(al) accessories | Change of product name |
| Change of performance data (including shelf life) | Change in clinical risk/benefit profile |
| Changes in the approved design (e.g. product specifications, materials, packaging, safety related functions, shelf life, software included in the device) | Change of sterilization processes (e.g. equipment, cycle parameters, load, chamber or facility) |
| Change of the incorporated medicinal substance, including its specification or changes in manufacturing or inspection processes of this substance | Change of the animal tissue utilized in manufacturing of the device, including its specification, changes of the supplier, manufacturing or inspection processes of this tissue |
| Change of substances/combination of substances to be absorbed by or locally dispersed in the human body, including its specification or changes in manufacturing or inspection processes of this substance | IVDR: In case of companion diagnostics:  Changes of the concerned medicinal product for which the companion diagnostic is essential for the safe and effective use, including claims, indications, contra-indications, warnings |
| Changes in materials or critical material suppliers | Changes in the manufacturing processes incl. e.g. equipment |
| Change of design facilities or manufacturing facilities, manufacturer or Authorized Representative / UK Responsible Person | Others (please specify): Enter text here |

**Remark**

Depending on the nature of the change, on-site audits may be required apart from the assessment of the respective design/technical documentation or product testing.

**Brief description of the changes**

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| Enter text here |

**Note:**

For product additions/name changes or additions or changed product related facilities the attachment of the TÜV Rheinland form“**Product List and Application**” (MDR: MS-0030497 / IVDR: MS-0034327/UK MDR: MS-0045276), or in case of IVDD/UK MDR “**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.

**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. |
| 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:   * EC Design-Examination Addendum Report (MDD/IVDD) * Revised Technical Documentation Assessment Report * On-site audit (in addition to documentation review) * Evaluation report (e.g. changes in sterilization, but not for Design Dossiers) * 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. |
| 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 | |  | |