The following information must be filled in by the company:

Details of the company

|  |  |
| --- | --- |
| Customer number |       |
| Company |       |
| Street |       |
| Postal code, place |       |
| Country |       |

**Contact person for questions**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Title | [ ]  | Mr. | [ ]  | Ms. | [ ]  | Dr. |
| First and last name |       |
| Position |       |
| Direct phone |       |
| Personal e-mail address |       |

**Information on affected products**

|  |  |
| --- | --- |
| Concerned product or product group |       |
| Concerned GMDN/UMDNS Code (for class IIb devices) |       |
| Concerned GIVD (EDMS) Code(for IVD products) |       |
| Registration number of concerned certificate/s |       |

According to the certification contract between mdc and the company planned changes are subject to notification. The following changes are planned or have been implemented:

**Organizational changes**

|  |  |
| --- | --- |
| [ ]  | Change of legal form or company name |
| [ ]  | Change of company address |
| [ ]  | Change of organizational structure |
| [ ]  | Change of ownership |
| [ ]  | Addition / deletion / relocation of business units, subsidiaries or manufacturing sites |
| [ ]  | Change of number of employees since the last audit: |
| [ ]  | 5 or more employees (company size up to 20 employees) |
| Number of employees so far: |       | Number of employees new: |       |
| [ ]  | More than 25% (company size over 20 employees) |
| Number of employees so far: |       | Number of employees new: |       |
| [ ]  | Change of personal responsibilities (Management, quality management representative, safety officer for medical devices, person responsible for regulatory compliance) |

**Description of the organizational change – if applicable**

|  |
| --- |
|       |

The following changes must be communicated to mdc **prior** to implementation, and appropriate supporting documentation must be submitted upon request, if applicable:

**Changes in the field of manufacturing, quality control and quality management system:**

|  |  |
| --- | --- |
| [ ]  | Change of manufacturing technology |
| [ ]  | Change of sterilization procedure |
| [ ]  | Change of special processes |
| [ ]  | Change of test procedures |
| [ ]  | Other significant changes affecting the quality management system |

**Changes regarding the approved product range (only for procedures according to Directive 93/42/EEC and 98/79/EC):**

|  |  |
| --- | --- |
| [ ]  | Change of critical suppliers (see [NBOG 2010-1](https://www.nbog.eu/nbog-documents/)) |
| [ ]  | Change of subcontractors |
| [ ]  | New product or product group to be certified |
| [ ]  | New product in already certified product group |
| [ ]  | Cancellation of a product or a product group |
| [ ]  | Change of intended use |
| [ ]  | Change of use of the product / of user group |
| [ ]  | Change of classification of the product |
| [ ]  | Change of performance characteristics and limitations |
| [ ]  | Change of raw materials / components |
| [ ]  | Change of medicinal substances / tissues or cells of animal origin, or their derivatives |
| [ ]  | Change of accessories |
| [ ]  | Change of stability / shelf-life / transport stability |
| [ ]  | Change of power supply of product |
| [ ]  | Change of CPU or other hardware |
| [ ]  | Change of software / operating system / algorithms |
| [ ]  | Change of labelling / instruction for use (IFU) |
| [ ]  | Change of technical file |
| [ ]  | Other changes (please describe): |
|       |

**Evaluation of the change by the manufacturer (only for procedures according to Directive 93/42/EEC and 98/79/EC):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is the change a “substantial” change in accordance with [NBOG 2014-3](https://www.nbog.eu/nbog-documents/)? | [ ]  | Yes | [ ]  | No |
| Is the change a “significant” change within the meaning of the [MDCG 2020-3](https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en) (MDD) or [MDCG 2022-6](https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en) (IVDD)? | [ ]  | Yes | [ ]  | No |
| Does the change potentially affect the risk analysis? | [ ]  | Yes | [ ]  | No |
| Does the change potentially affect compliance with the general safety and performance requirements? | [ ]  | Yes | [ ]  | No |

**Description of the change including justification as to why it is or why it is not a substantial change:**(please specify affected products with full name and REF)

|  |
| --- |
|       |

**Documentation of the change in the quality management system and/or in the technical documentation:**(Listing of the documents and records concerned)

|  |
| --- |
|       |

**Reason for the change:**

|  |
| --- |
|       |

**Potential impact on compliance with the general safety and performance requirements:**

|  |
| --- |
|       |

**Date/period of implementation of the planned change:**

|  |
| --- |
|       |

|  |
| --- |
| ***NOTES ON DATA PROTECTION:*** *The processing of the personal data communicated in this notification of change takes place at the request of the signatory/the submitting person for the purpose of the execution of an existing contract according to Art. 6 Para. 1 lit. b GDPR. For any further use of personal data, the consent of the data subject is regularly required. Further information on data protection can be found in our data protection declaration online at* [*https://www.mdc-ce.de/privacy.html*](https://www.mdc-ce.de/privacy.html)*.* In accordance with data protection legislation, you have the right to information, correction, restriction and deletion of your personal data. In addition, you have the right to revoke the processing of personal data. If you wish to exercise any of these rights or have any further questions about data protection, please send an e-mail to datenschutz@mdc-ce.de. |

|  |  |  |
| --- | --- | --- |
|       |  |       |
| Place, Date |  | Signature or full name in case of electronic transmission |

The following information will be filled in by mdc:

Evaluation of the notification of change:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is the manufacturer's notification of change to be classified as a “substantial” change according to [NBOG 2014-3](https://www.nbog.eu/nbog-documents/)? | [ ]  | Yes | [ ]  | No |
| Is the manufacturer's notification of change to be classified as a “significant” change within the meaning of the [MDCG 2020-3](https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en) (MDD) or [MDCG 2022-6](https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en) (IVDD)? | [ ]  | Yes | [ ]  | No |
| Justification in case of a differing opinion on the manufacturer's classification: |
|       |

**Measures required:**

|  |
| --- |
| Response to the manufacturer required? |
|[ ]  No |
| [ ]  | Yes, done on: |       | By mail: |[ ]  By e-mail: |[ ]
|  | [ ]  | Confirmation letter positive (verification within the framework of the next audit) |
|  | [ ]  | Confirmation letter positive (verification within the scope of sampling) |
|  | [ ]  | Acknowledgement of receipt and initiation of further steps (e.g. request for technical documentation): |
|  |  |       |
|  | [ ]  | Other: |
|  |  |       |
| Update of sampling plan |
| [ ]  | No | [ ]  | Not applicable for IVD |
| [ ]  | Yes, done on: |       |
| [ ]  | Information of the audit team for the next audit |
| [ ]  | Assessment by auditor/expert with test report on the following aspects: |
|  | [ ]  | Special audit |
|  | [ ]  | Review of documents: |
|  |  | [ ]  | Decision clinical coordination required |
|  |  | [ ]  | Complete techn. documentation | [ ]  | Clinical evaluation | [ ]  | Instruction for use (IFU) |
|  |  | [ ]  | Electronic IFU | [ ]  | Labelling | [ ]  | Results of product tests |
|  |  | [ ]  | Performance data | [ ]  | Other: |       |
|  |  | [ ]  | Validation data. If yes, which:(e.g. sterilisation, software) |       |
|[ ]  Consultation with the competent authority for products which require specific procedures |
| [ ]  | Preparation of order confirmation with the following expenses and assessors: |
|  |       |
| Changes of the specific criteria for batch testing |
| [ ]  | No |
| [ ]  | Yes, the following changes: |       |
|  | Information to PEI necessary? |
|  | [ ]  | Yes, done on: |       | [ ]  | No |
| Supplement to the certificate necessary? |
| [ ]  | Yes | [ ]  | No |
|  | Notes on the supplement to the certificate: |
|  |       |
|  | Related certificate: |       |
| [ ]  | Fee for amendments / extensions / changes according to price list |
| [ ]  | Other costs (e.g. third-party costs): |       |
| Other remarks: |
|       |

|  |  |  |
| --- | --- | --- |
|       |  |       |
| Date |  | Signature project management mdc |