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 concerned generic device group / category of device according to[MDCG 2019-13](https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en) |       |
| Concerned Basic UDI and UDI-DI |       |
| Concerned EMDN Code (only for class C) |       |
| 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 **(Notification of Change must be submitted before implementation!)** |
| [ ]  | Change of company address **(Notification of Change must be submitted before implementation!)** |
| [ ]  | Change of organizational structure |
| [ ]  | Change of ownership |
| [ ]  | Addition / deletion / relocation of business units / subsidiaries / 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, responsible person (PRRC), authorised representative) |

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

|  |
| --- |
|       |

The following changes must be notified to mdc in any case **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 Regulation (EU) 2017/746):**

|  |  |
| --- | --- |
| [ ]  | Change of critical suppliers |
| [ ]  | Change of subcontractors |
| [ ]  | New product or generic device group / category of device to be certified |
| [ ]  | New product in already certified generic device group / category of device |
| [ ]  | Cancellation of a product or generic device group / category of device |
| [ ]  | 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 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 Regulation (EU) 2017/746):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Is the change a substantial change to the QM system or the device-range covered by it in accordance with Regulation (EU) 2017/746 Annex IX, Section 2.4? | [ ]  | Yes | [ ]  | No |
| Does the change concern a device certified by an EU certificate in accordance with Regulation (EU) 2017/746 Annex IX, Section 2.4 and could it affect the safety and performance of the device or the conditions prescribed for use of the device (within the meaning of IVDR Annex IX, section 4.11)? | [ ]  | 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:**

|  |
| --- |
|       |

**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 notified change by the manufacturer to be classified as a substantial change in accordance with Regulation (EU) 2017/746 Annex IX, Section 2.4 (concerns QMS certificates in accordance with IVDR Annex IX, Chapter I or Annex XI, Part A)? | [ ]  | Yes | [ ]  | No |
| Is the notified change by the manufacturer to be classified as a change in accordance with Regulation (EU) 2017/746 Annex IX, Section 4.11 (concerns TD certificates in accordance with IVDR Annex IX, Chapter II)? | [ ]  | Yes | [ ]  | No |
| Justification in case of a differing opinion on the manufacturer's classification: |
|       |

**Measures required:**

|  |
| --- |
| Assessment by an auditor / expert required? |
|[ ]  No |
|[ ]  Yes, done on: |       |
|  | Result: |       |
| 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 audit programme required? |
| [ ]  | No | [ ]  | Yes, done on: |       |
| Update of sampling plan required? |
| [ ]  | No | [ ]  | Yes, done on: |       |
| Does the resource planning need to be adjusted? (Involvement of the Head of Notified Body required) |
| [ ]  | No | [ ]  | Yes, done on: |       |
| Further measures: |
| [ ]  | 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 |
|  |  | [ ]  | Compl. Techn. Documentation | [ ]  | Clinical evaluation | [ ]  | Performance data |
|  |  | [ ]  | Instruction for use (IFU) | [ ]  | Labelling | [ ]  | Results of product tests |
|  |  | [ ]  | Other: | [ ]  |       |
|  |  | [ ]  | Validation data. If yes, which: (e.g. sterilisation, software) |       |
|[ ]  For products of class D: Verification of manufactured products[[1]](#footnote-2) |
|  | Change of criteria for batch release |
|  | [ ]  | No | [ ]  | Yes, following change: |       |
|  | Information to expert laboratories of the EU Commission / reference laboratory necessary? |
|  | [ ]  | No | [ ]  | Yes, done on: |       |
| [ ]  | Preparation of offer with countersignature with the following expenses and assessors: |
|  |       |
| [ ]  | Preparation of offer with contract with the following expenses and assessors: |
|  |       |
| [ ]  | Preparation of order confirmation with the following expenses and assessors: |
|  |       |
| Change of certificates necessary? |
| [ ]  | Yes | [ ]  | No |
|  | [ ]  | Issue of a new certificate with remaining validity period of the previous certificate |
|  | [ ]  | Amendment to the EU Quality Management Certificate |
|  | [ ]  | Amendment to the EU Technical Documentation Assessment Certificate |
|  | Notes on required drafts (e.g. extension of scope of the certificate): |
|  |       |
|  | Number of father certificate for draft: |       |
|  | [ ]  | Draft created, draft no.: |       |
| [ ]  | Fee for amendments / extensions / changes according to price list |
| [ ]  | Fee for issue of certificates according to price list |
| [ ]  | Other costs (e.g. third-party costs): |       |
| Other remarks: |
|       |

|  |  |  |
| --- | --- | --- |
|       |  |       |
| Date |  | Signatur project management mdc |

1. See Regulation (EU) 2017/746 Annex IX, Chapter II, Section 4.12 [↑](#footnote-ref-2)