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 |  | | | | | |

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** *(Please submit up-to-date and meaningful supporting documents, e.g. extract from the commercial register,*

*extract from the company register, organisation chart, etc.)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Change of legal form or company name | | | | |
|  | Change of company address | | | | |
|  | Change of organizational structure | | | | |
|  | Change of ownership | | | | |
|  | Business units, subsidiaries or manufacturing sites to be added, relocated or deleted | | | | |
|  | Change of number of employee 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) | | | | |

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

|  |
| --- |
|  |

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

**Changes in the field of quality management system, activities/products:**

|  |  |
| --- | --- |
|  | Change in products, e.g. inclusion or omission of products (manufacturer, EC Rep., importer) |
|  | Change of activities/services |
|  | Change of production technology, e.g. clean room, e.g. materials used |
|  | Change of an outsourced process or subcontractor |
|  | Other significant changes affecting the quality management system |

**Description of the change:**(please specify affected products with full name and REF)

|  |
| --- |
|  |

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

|  |
| --- |
|  |

**Reason for the change:**

|  |
| --- |
|  |

**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 document Data protection information for customers and interested parties in the download area at* [*www.mdc-ce.de/en*](https://www.mdc-ce.de/en/service-portal/downloads/)*.* 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](mailto: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 notified change to be classified as a significant change?  (see also PB "Processing of NOCs including QM supplements" (ID10771) and IAF MD9:2023) |  | Yes |  | No |
| Examples of significant changes (not exhaustive):  - Change of company name / owner  - Change within the scope of application (QM system, activities/products)  - Change in locations (address, scope, activities)  - Change in responsibilities / authorisations with regard to the QM-system | | | | |

**Measures required:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Is a technical assessment by an auditor / technical expert required? | | | | | | | |
|  | No | | | | | | |
|  | Yes, carried out on: |  | | | | | |
| Result: |  | | | | | |
| Updating of the audit programme required? | | | | | | | |
|  | No |  | Yes |  | | | |
| Adjustment of the calculation and confirmation by the organisation required? | | | | | | | |
|  | No |  | Yes |  | | | |
| Does the audit team need to be adapted? | | | | | | | |
|  | No |  | Yes |  | | | |
| Additional audit (interim audit) required? | | | | | | | |
|  | No |  | Yes |  | | | |
| Change of certificates required? | | | | | | | |
|  | No |  | Yes (creation of a new certificate with remaining term of the original certificate) | | | | |
| Does the amended certificate data match the information in the submitted verification documents? | | | | | | | |
|  | No |  | Yes |  | N/A | | |
| Further measures: | | | | | | | |
|  | Information of the audit team for the next audit | | | | | | |
|  | Other measure: | | | | | | |
|  |  | | | | | | |
| Feedback to the organisation required? | | | | | | | |
|  | No |  | Yes |  | | | |
|  | | | | | |  |  |
| Date | | | | | |  | Signature project management mdc |