

Customer number

Company

Street

Postal code, place

Concerned product /
product group

Registration number of
concerned certificate

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

Organizational changes:

- Change of legal form or name of the company
- Change of company address
- Change of organizational structure
- Change of proprietor
- Business units, subsidiaries or manufacturing sites to be added or deleted
- Change of number of employees since the last audit
 - more than 25% (at companies with more than 20 employees)
 - 5 or more employees (at companies with 20 or less employees)
- Change of personal responsibilities (management, quality management representative)
- Change of suppliers
- Change of subcontractors

Changes in the field of manufacturing and quality control:

- Change of manufacturing technology
- Change of sterilization procedure
- Change of special processes
- Change of test procedures

Changes regarding products:

- 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
- 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/instructions for use
- New information regarding risks in connection with the product
- Change regarding compliance with harmonized standards or essential requirements
- Change of technical file

Other changes:

Manufacturer's estimation regarding importance of the change:

Risk analysis is concerned: yes no

Compliance of general requirements is concerned: yes no

Description of the change:

Documentation of the change in the quality system / in the technical file:
(list of documents and records)

Reason for the change:

Possible effects on the compliance with the Essential Requirements:

date, name, signature, company stamp

Initial assessment by the Notified Body:

- processing by project coordination
- Information of the audit team for the next audit
- review by auditor/expert is necessary
- new certificate / amendment to the EC-design examination certificate is necessary

date, signature project manager mdc