# Appendix G

Change of notified body/certification body

Product Service

**Manufacturer:**

**Application identification:**

☐ Voluntary change
☐ Enforced change

## Change applicable for

☐ 93/42 EEC (MDD)
☐ EN ISO 13485
☐ 98/79 EC (IVDD)
☐ 90/385 EEC (AIMDD)

## Validity of the certificate(s)

☐ Use validity of the existing certificate(s)
☐ Issue of certificate with a new period of validity*

* In the case of EC procedures, Appendix E is required for issue of certificates with a new validity period.

## Adjustments/corrections

☐ No adjustments/corrections required
☐ Within the scope of the transfer, the following minor adjustments/corrections must be made to the certificate:

## List of documents to be enclosed with the application

Please submit the following documents (if applicable):

1. All documents based on the document “Request for information concerning the change of notified body or certification body”.

   If these documents have already been submitted prior to the application, the following applies:
   ☐ Documentation has been submitted in full and continues to be valid.
   ☐ The documentation submitted so far is incomplete. The complete documentation is submitted with this application.

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Product Service

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**Application identification:**

## List of documents to be enclosed with the application

2. Approvals from current certification body/notified body for significant changes since last (initial or extension) audit/assessment

3. In case of transferring a quality management certificate:
   - Management System Manual
   - Actions taken by the organization to address noted nonconformities for most recent audit and technical documentation reviews including approval
   - Customer complaints: All open cases and cases within the last 12 months including their status and actions taken
   - List of outsourced processes including the respective suppliers
   - Procedures for critical processes

   **EC only in case of MDD Class IIa and IIb:**
   Reports from technical documentation review and technical documentation sampling plan

   **EC only:**
   - Vigilance reports: All open cases and cases within the last 12 months including their status and actions taken
   - Field safety notices/field safety corrective actions (FSN/FSCA): All open FSN/FSCAs and all cases within the last 12 months including their status and actions taken

4. In case of transferring a product certificate (design or type testing/EC type examination):
   - Current version of Design Dossier/technical documentation
   - Medicinal substance or HO: Consultation file (for combination products or in case of human origin)
   - Medicinal substance or HO or AO: Response of Competent Authority (for animal origin (TSE/BSE-relevant); combination products; human origin) including actions taken
   - Medicinal substance or HO or AO: Decision of notified body (in case of consultation)
   - AO: EDQM certificate(s) (in case of animal origin (TSE/BSE- and SER-relevant))
   - In case of type testing: Sample of the product