

Form



Product Service

Change Notification Approval of Significant Change

This form is to be filled in by TÜV SÜD Product Service only.

TÜV Project No.:	_____	Department:	MHS _____
Applicant:	_____	Client No.:	_____
Contact Person:	_____	Fax:	_____
Change Notification ID:	_____	Date:	_____
Affected Certificate(s):	_____		
Subject:	_____		

Classification of the change:

- Significant Change, new or updated certificate **does not need** to be issued (approval by MHS)
- Significant Change, new or updated certificate **needs** to be issued (approval by Certification Body CRT2)

Action required:

- Contract Review
- Assessment of documents necessary
- Re-assessment of QM system necessary (audit)
- Re-assessment of product necessary (design dossier review, testing)
- Others: _____

Documentation of assessment:

- Additional report is not necessary. This form serves as evidence of assessment performed (please see chapter *Comments*).
- Documentation review report Date: _____
- Audit report Date: _____
- Technical report Date: _____

Verification of implementation:

- Verification of implementation will be check during next audit Date of audit planned: _____
- Implementation was checked during audit Date of audit: _____
- _____

Comments:

Recommendation:

- The change may be approved
- The change cannot be implemented
- Certificate (attachment) may be issued

_____ **Name:** _____ **Signature:** _____
Date Auditor or Product Specialist

Decision:

Decision by: Certification Body (CRT2) or MHS

- TÜV SÜD Product Service cannot confirm that after implementation of the change submitted the quality system or product still meets the applicable requirements of the directive.
- Herewith, TÜV SÜD Product Service confirms that after implementation of the change submitted the quality system or product still meets the applicable requirements of the directive.

_____ **Name:** _____ **Signature:** _____
Date TÜV SÜD Product Service, Notified Body 0123