*Please complete all relevant sections of the form and submit it to HTCert.*

*Significant changes are often related to both products and systems; multiple checks might be required.*

|  |  |
| --- | --- |
| Company name |       |
| Company address |       |
| Contact person |       |

**Nature of Change**

|  |
| --- |
| **Organizational changes** |
| [ ]  | Change of legal entity or company name  |
| [ ]  | Change of company address |
| [ ]  | Change of business sites |
| [ ]  | Change of contact person |
| [ ]  | Change of responsible persons (management representative, qualified person) |
| [ ]  | Change of number of employees more than 25% |
| [ ]  | Change of authorised representative |
| [ ]  | Change of subcontractors |
| [ ]  | Change of critical suppliers |
| **Changes related to QMS**  |
| [ ]  | Change of manufacturing process |
| [ ]  | Change of sterilization process |
| [ ]  | Change of testing process |
| [ ]  | Post market surveillance  |
| **Product related changes** |
| [ ]  | Addition of new products |
| [ ]  | Removal of certified products |
| [ ]  | Change of product name |
| [ ]  | Change of intended use |
| [ ]  | Change of specifications |
| [ ]  | Change of materials |
| [ ]  | Changes of software |
| [ ]  | Change of labelling |
| **Other changes** |
| Please specify       |

|  |
| --- |
| **Description of the planned change:***Please describe the nature of the change(s) and, where applicable, provide a comparison of before and after.* |
|       |
| **Date / timeframe of implementation of planned change:** |
|       |
| **Reasons for the change:** |
|       |
| **Additional Documents submitted:** |
|       |

|  |  |  |  |
| --- | --- | --- | --- |
| **Submitted by:** |       | **Date:** |       |

**HTCert review**

Is the change substantial? **[ ]** Yes [ ]  No

|  |
| --- |
| **Actions Required** |
| [ ]  | No action required | [ ]  | Additional information from client |
| [ ]  | Contract review | [ ]  | Modification of assessment program |
| [ ]  | Update of database | [ ]  | Update of the EC certificate |
| [ ]  | Assessment of technical documentation | [ ]  | Assessment of QMS documentation |
| [ ]  | Special audit | [ ]  | Review during next on-site audit |
| [ ]  | Other,       |

|  |  |  |  |
| --- | --- | --- | --- |
| **Reviewed by:** |       | **Date:** |       |