*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:** |  |