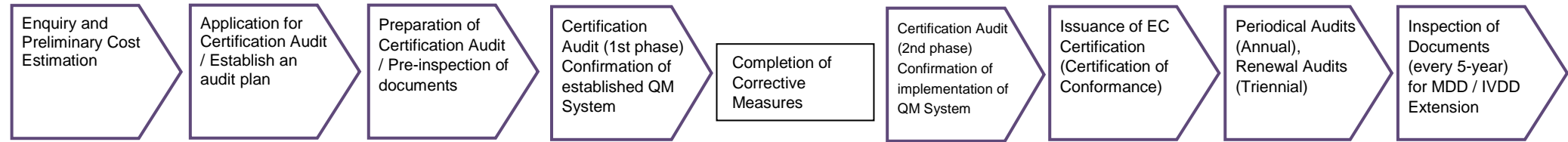
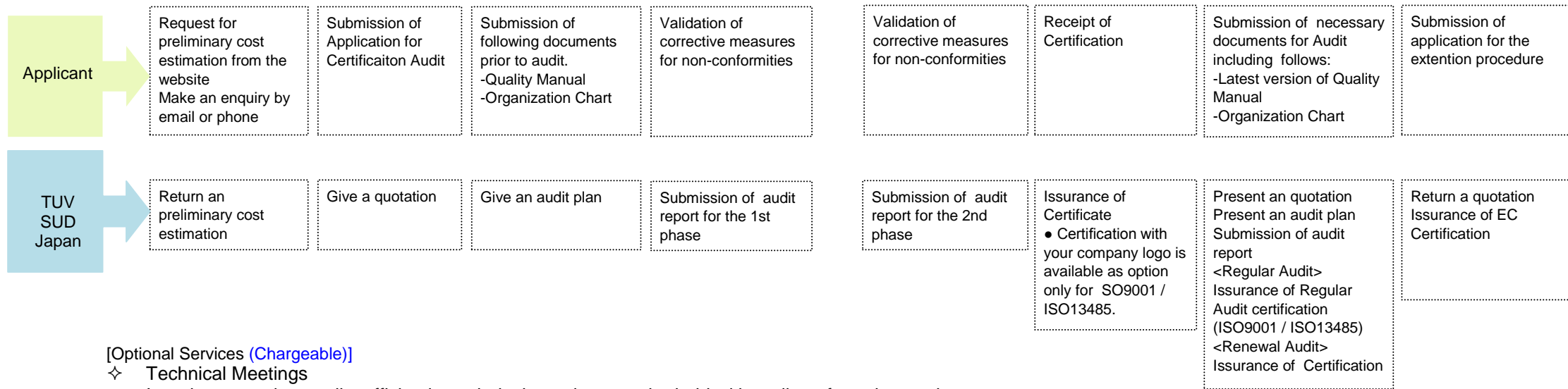




Procedure for Quality Management System Certifications (ISO Certification / CE Marking)
 Target Standards /Directives: ISO9001 / ISO13485 / CMDCAS / MDD Annex V, Annex II.3/ IVDD Annex VII, Annex IV.4



Renewal audits are applicable to the ISO



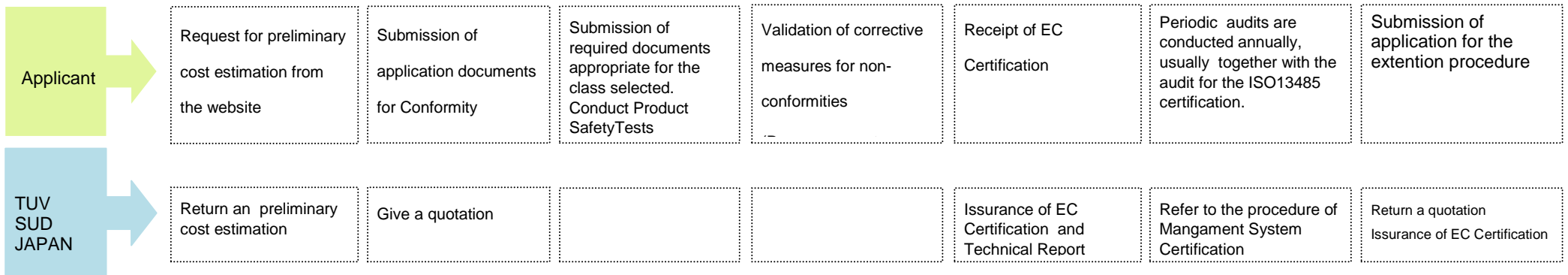
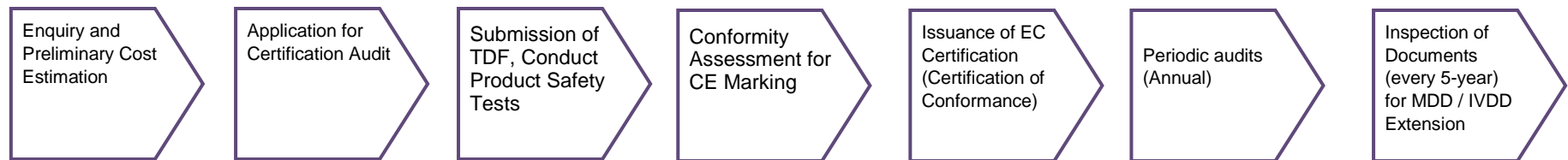
[Optional Services (Chargeable)]

- ◇ Technical Meetings
In order to conduct audits efficiently, technical meetings can be held with auditors from time to time upon request.
- ◇ Pre-check for certification audit (This service is available for the first time only.)
Prior to a certification audit, we will visit your company to identify how well your QM system has achieved so far.
Note: Receiving this inspection does not mean that non-conformities will not be found in the certification audits and it is not a substitute for the 1st phase audit.
- In principle, the third party audits are not required for products classified as Class I under the MDD and CMDCAS. However, Class I medical devices with measuring function and Class I sterile products require third-party audits.
- Conformity assessments for CE marking (MDD Annex II.3, V / IVDD Annex VII and Annex IV.4) can be conducted in parallel with the assessment of the QM system.
- The identification number of TUV-SUD Product Service as a Notified Body is "0123", and is affixed to the CE mark.

Procedure of TDF (Technical Document File) Assessment

(Conformity Assessment for CE Marking)

Target Directives: MDD Annex III, II.4, IVDD Annex V, IV.4



[Optional Services (Chargeable)]

- ✧ Technical Meetings
In order to conduct audits efficiently, technical meetings can be held with auditors from time to time upon request.
Note: No consulting services will be provided.
- The identification number of TUV-SUD Product Service as a Notified Body is "0123", and is affixed to the CE mark.