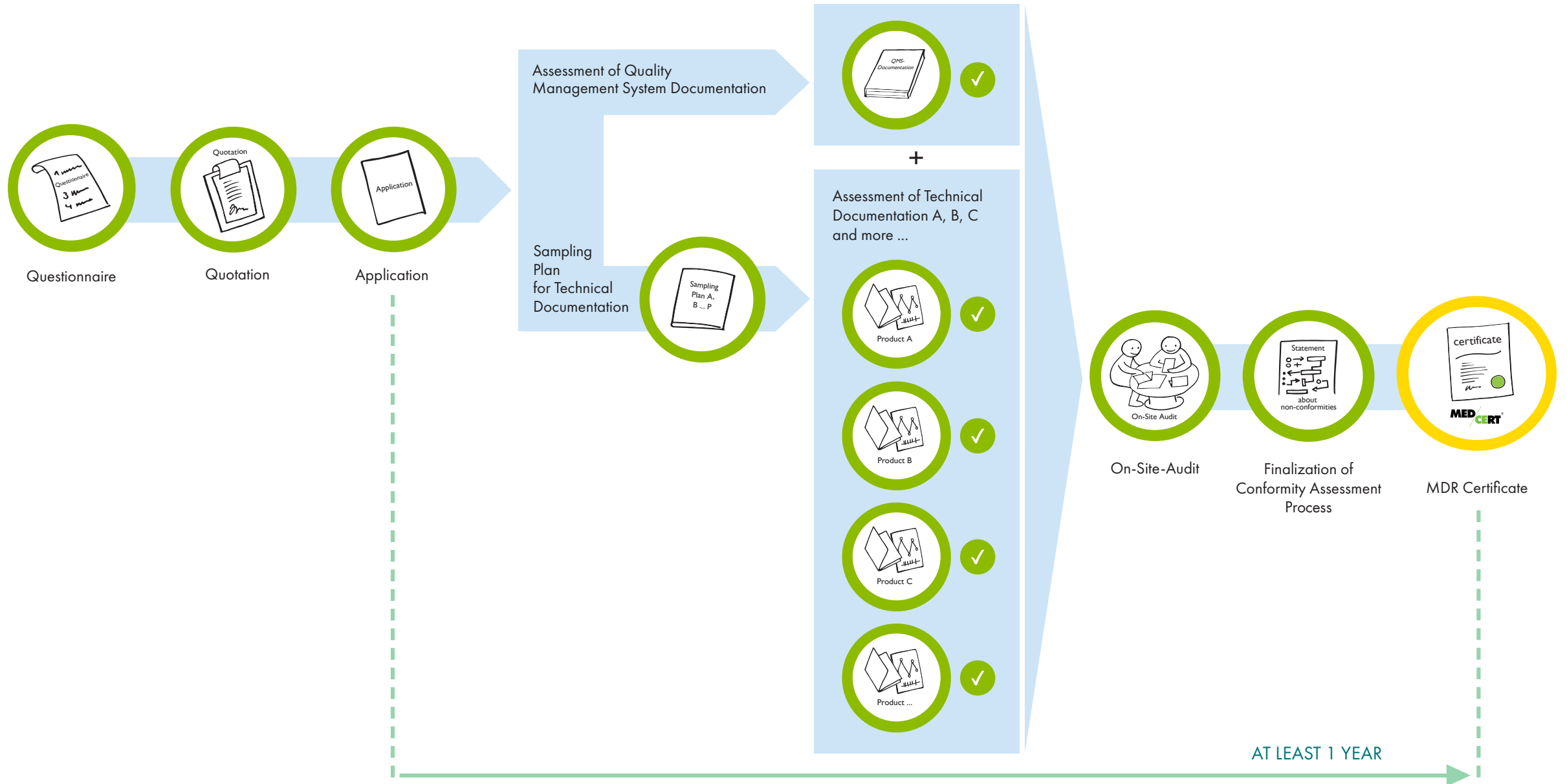


MDR - Medical Device Regulation 2017/745

INITIAL CONFORMITY ASSESSMENT PROCESS



VERY IMPORTANT:

Please note that many non-conformities or major non-conformities occurred in the assessment of the Quality Management System Documentation and/or in the assessment of the Technical Documentation(s) may delay the planning and execution of the audit. This would postpone the finalisation of the conformity assessment process and consequently the issuance of the MDR Certificate. In this case the current MDD Certificate already could have expired before the new MDR Certificate was issued.