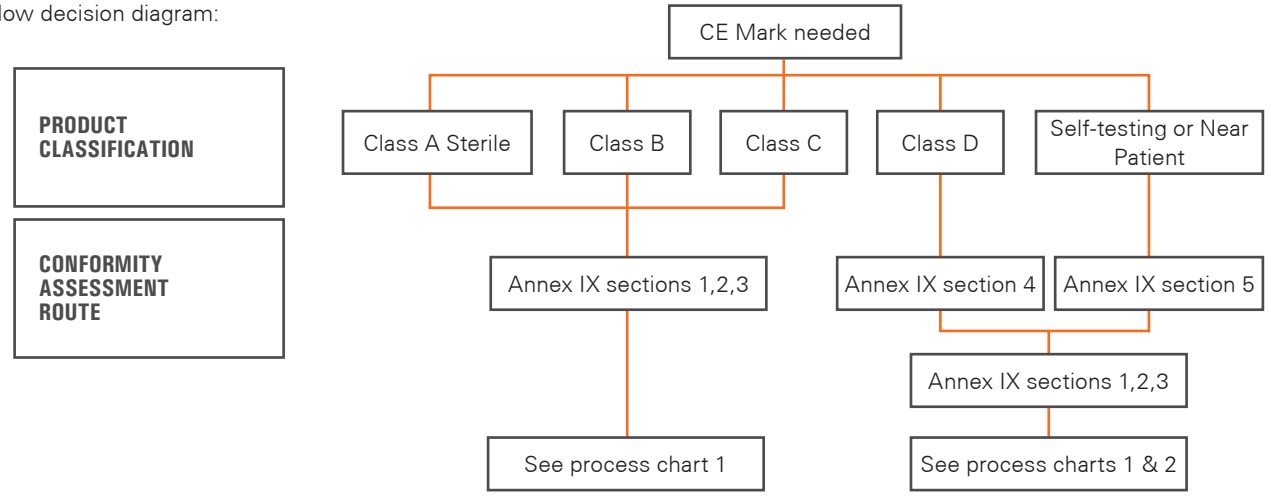
YOUR CERTIFICATION PROCESS EXPLAINED

If you wish to get CE marking for your IVD medical device according to IVD medical device regulation (EU) 2017/746, please see below how SGS can help you. SGS United Kingdom Ltd. is a Notified Body for your range of devices and certification will be undertaken as Notified Body 0120. This means you are entitled to use CE 0120 on devices within your scope on the completion of a successful audit and technical documentation assessment. Class D devices must additionally have a Technical Documentation Assessment certificate (Annex IX section 4&5) before using CE 0120.

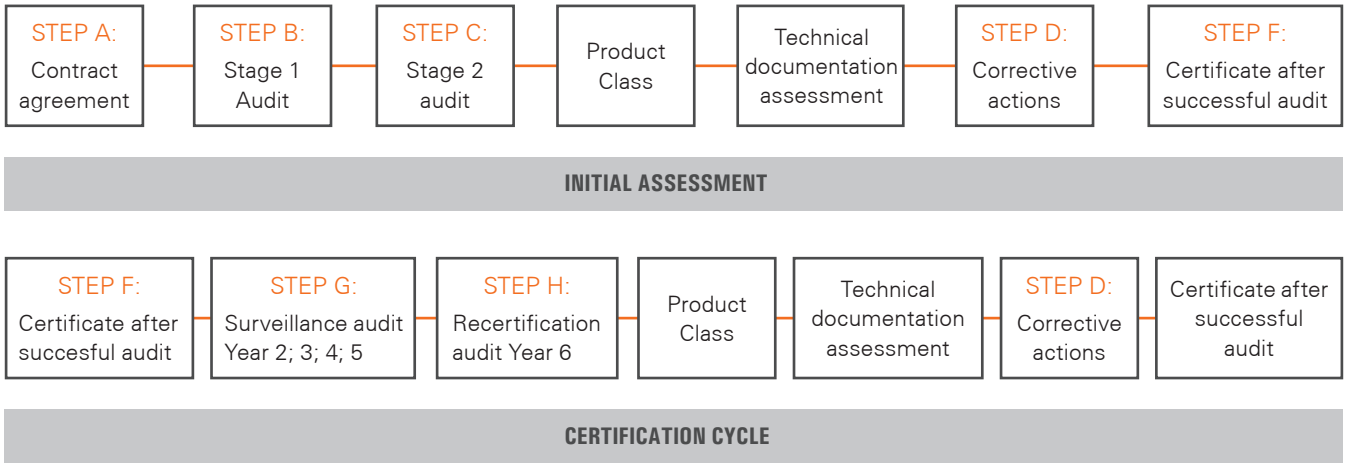
The first step for you will be to determine your device(s) classification according to rules defined in Annex VII of the Regulation (EU) 2017/746. SGS United Kingdom Ltd. offers the conformity assessment route based on Quality Management System (QMS) and assessment of technical documentation as per Annex IX of the Regulation (EU) 2017/746.

To apply for certification and to start the assessment process, you must complete the "Application Form" (insert link on the application form that would bring the customer to the complete application form (GPMDREG 1001), sign it and return to your SGS delivering office (insert link on delivering office - delivering office contact's details based on clients localisation). We recommend these to be done as soon as your decision to proceed has been taken to allow maximum time for planning. Your application will be processed, and we will contact you to arrange the next steps of the audit process and dates.

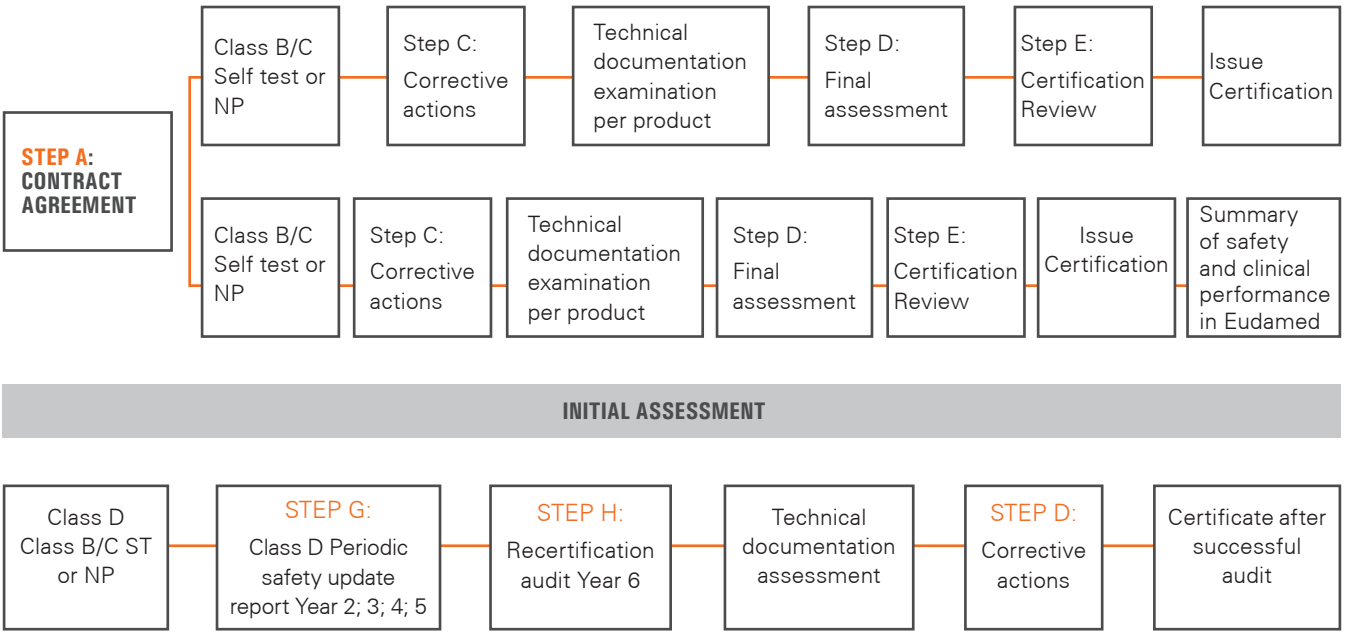
See below decision diagram:



PROCESS CHART 1:



PROCESS CHART 2:



To get more details on each certification process or on specific steps, do not hesitate to contact your delivering office.

SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY