

Dear Medical Devices Customers,

As a consequence of the COVID19 pandemic, the EU Commission worked on a proposal to maintain the current MDD system and postpone the date of application of the MDR application for one year beginning of April 2020. This proposal has now been approved by the European Parliament, therefore the transition period for the implementation of the MDR and thus the transition period for MDD certification has been extended until May 2021.

As previously, SGS has implemented a cut-off date for any new MDD activities of the 30th November 2020 as, according to MDR transitional provision (article 120) and implementing act (EU) 2020/558 approved on the 23rd April 2020, we will not be allowed to issue any CE MDD certificates after 25th May 2021. This cut-off date provides SGS a sensible period of time to fully complete any MDD work started before the end of November 2020, to allow us to ensure those MDD certificates can definitely be issued before the end of the MD Directive transition in May 2021 to effectively support you.

What does the cut-off date fixed on the 30th November 2020 mean?

- **No new initial onsite audits** will be done after 30th Nov 2020, but we will continue to support you to close out existing CAR and TCAR already issued from audits prior to the cut-off, to provide you with a CE certificate before 24th May 2021.
- **No scope extension under MDD after 30th Nov 2020:** No onsite audit or technical file review for CE scope extension will be done after 30th Nov 2020 but we will continue to support you to close out existing CAR and TCAR already issued from Extension to Scope reviews prior to the cut-off, to provide you with a CE certificate before 24th May 2021.

What about CE Certificate validity and recertification due date?

The MDD CE certificate issued by SGS shows a five-year validity date (expiry date) and a recertification due date that is three years from issue. The recertification due date is linked to your ISO 13485 certification cycle (hence three years), which allow us to deliver combined audits. This is why your CE certificate validity is in general 2 years longer than the specified recertification activity.

For those customers who are due a recertification audit after our cut-off date, we will conduct the ISO 13485 recertification audit as planned but instead of doing recertification under MDD at the same time we will only conduct a surveillance audit (V4). This will include on site audit and technical file sample review and is intended to maintain the continued validity of your MDD certification. Likewise, for the following year, we will perform a further surveillance audit activity only (V5) until the end of your CE certificate validity. We will not be able to re-issue any new certificates, so you will remain using your current issued certificate.

- **Example:** The MDD CE certificate is valid until the 2nd May 2022 but it also indicates the three-year cycle recertification due date is on 18th March 2020. For this case, SGS will perform V4, and then V5 surveillance audits in relation to MDD only until the certificate reaches its expiry date.



For Class III Annex II section 4 certificates which are standalone certification and have 5 years validity, if their expiry date is in 2020 or early 2021 then we will conduct re-certification audits to allow the full transition period for MDD certificates until 2024 to be used.

What about early recertification?

To be able to provide dedicated resource to all our current clients, SGS will **not perform any early recertifications**. Some exceptional cases may be considered but they will always be managed as second level of priority compared to the ongoing support for all our existing clients. There is **no guarantee** that we can provide early recertification, as we cannot guarantee that all conformity assessment activity can be fully completed before 25th May 2021. This means that we can't or extend the existing validity of certificates. Please if you consider that your company maybe in this exceptional circumstance, please contact your local Medical Device Office:

SGS XXX,

Phone:

Email:

Be assured that you can count on SGS during this trouble time to support you and your activities the best way we can.

Best Regards