Dear Medical Devices Customers,

SGS are actively preparing for the transition to the new European Regulation MDR (EU) 2017/745 and we would like to inform you of the following timelines that should allow us to work with you to achieve MDR transition in an easy and straightforward way.

We have implemented a cut-off date for any new MDD activities of the 30th November 2019 as, according to MDR transitional provision (article 120), we will not be allowed to issue any CE MDD CE certificate after 25th May 2020. This cut-off date provides SGS a sensible period of time to fully complete any MDD work started before the end of November, to allow us to ensure those MDD certificates can definitely be issued before the end of the MD Directive transition in May 2020 to effectively support our customers.

**What does the cut-off date fixed on the 30th November 2019 mean?**

- **No recertification of MDD CE certification after 30th Nov 2019:** No new recertification onsite audits or technical file reviews will be done after 30th Nov 2019, 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 2020.

- **No scope extension under MDD after 30th Nov 2019:** No onsite audit or technical file review for CE scope extension will be done after 30th Nov 2019 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 2020.

**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 that 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 is 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 only until the certificate reaches its expiry date.
What will happen, if I don’t have any valid certificate after 25th May 2020?

You will lose the CE Mark for concerned product on that MDD certificate and must transition to MDR to be able to further apply the CE Mark for your devices.

What about an 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 scheduled recertifications and the ongoing support for all our clients. There is 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 2020. This means that we can’t provide certificates with longer validity or extend the existing validity of certificates.

What next?

To prepare your transition from MDD to MDR, we are asking you to complete the attached transition plan and send it back your local office at least one year in advance of your proposed transition date in order that we can consider your desired timelines in our preparations, to support your business needs as well as we can.

SGS medical device team remains at your disposal if you still have any questions on the transition phase. We will contact you soon again to initiate transition to MDR under a defined plan and agreed conditions.