Dear Manufacturers,

As you may already know, the EU parliament voted last week in favour of extending the deadlines of the MDR (EU) 2017/745 transition. This decision was mainly taken to avoid any medical device shortage on the European Market.

The approved text is granting an automatic extension of the MDD certificate validity till 31st December 2027 for Class III & Class IIb implantable devices and 31st December 2028 for other devices.
However, the following conditions are to be met:

1. Devices continue to comply with MDD
2. There are no significant changes in design and intended purpose
3. the devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, nor to other aspects of the protection of public health
4. Manufacturers must have a quality management system compliant with MDR (EU) 2017/745 article 10(9) before 26 May 2024
5. Manufacturers or their authorized representatives has lodged a formal application with a notified body before 26 May 2024 and a signed contract covering devices for transition before 26 September 2024 for the devices covered within the MDD certificate.

For MDD certificates that have already expired, the aforementioned condition 5 is replaced by either having a contract signed for MDR with a Notified body or having a derogation issued by a European competent authority before certificate has expired.

The voted text is emphasizing that appropriate surveillance activity for the maintenance of the MDD certificate shall be conducted by the Notified Body having issued the MDD certificate except if an agreement is put in place with the Notified body in charge of MDR conformity assessment. In SGS, we will conduct at least systematic regular on-site surveillance to maintain issued MDD certificate. We will continue conducting technical file reviews on a sampling basis for Class IIa and IIb products over the transition period. In addition, based on future guidance received from the commission or our risk assessment we may include partial assessment of Class III devices as well within this period. To allow the above, we need to establish a new contract and associated proposal with you if you wish to extend the validity of your MDD certificate within the transition period. Please note that the validity of the current certificate is extended and that NO new certificate will be issued as it is again the law.

As the conditions are determined based on lodging an MDR application and signing an MDR contract with a Notified Body, we are strongly encouraging you to contact your local medical device office to initiate the process of MDR conformity assessment as soon as possible to avoid last minute rush. We shall manage start of transition to MDR of all our MDD certified manufacturers in the next 18 months, and while the time is limited, we will do our best to support you transition within your defined timelines.

However, since signing contract can take up in between 2 to 6 months, we would require those who wish to go through this process to submit application to us as soon as possible.

For any further question, please contact your local medical device office.

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