FREQUENTLY ASKED QUESTIONS

NEW MEDICAL DEVICE REGULATIONS (EU) 2017/745 AND IN VITRO DIAGNOSTIC DEVICE REGULATIONS (EU) 2017/746

WHEN WERE THE NEW REGULATIONS PUBLISHED AND WHEN DO THEY COME INTO EFFECT?

Both the MDR and IVDR were published in the EU Official Journal on the 5th May 2017, and formally came into force on the 25th May 2017, 20 days later. The MDR becomes fully applicable after a 3-year transition period on 26th May 2020 and for the IVDR this is after a 5-year transition, on 26th May 2022. Some requirements of the Regulations will apply earlier than this (for example those for Notified Bodies or the Medical Devices Coordination Group) or can only apply once EU systems are in place (such as for UDI labelling and all aspects of EUDAMED).

WHAT DOES THE TRANSITION PERIOD MEAN AND WHAT WILL DEVICES HAVE TO COMPLY WITH?

The MDR and IVDR are now in their transition phase, at the end of this phase (26th May 2020 for MDR and 26th May 2022 for IVDR) then the current legislation of the Medical Devices Directive 93/42/EEC and IVD Directive 98/79/EC will be repealed and will no longer apply in the EU. In the transition phase a device could be CE Marked under either the current Directives, or the new Regulations (if they are fully compliant) but this is dependent on the designation of Notified Bodies to the new Regulations and expiration date of certificate under Directives. In addition, for some Class III and IIb medical devices, the Medical Device Coordination Group (MDCG) and the EU expert panels will need to be set-up and in place for the clinical evaluation consultation procedure to take place, without which they cannot be placed on the market.

WHEN WILL NOTIFIED BODIES FOR THE NEW REGULATIONS BE DESIGNATED AND BE ABLE TO ISSUE CERTIFICATION?

SGS has made the formal applications under MDR and IVDR and is actively progressing towards achieving Notified Body status. According to the recently published NBOG guidance 2017-1 (rev.1): "Designation and notification of conformity assessment bodies", SGS is expecting to be designated as soon as possible, which according to the outline plan by the European Commission is expected to be around mid to late 2019 for any Notified Body.

WHAT SCOPE WILL SGS BE EXPECTING UNDER THE MDR?

To continue to support all our existing clients, SGS expects a designation scope covering most devices (with the exception of active implantable medical devices which we currently do not cover). Our application under MDR will be extended to include those categories of devices which did not require a Notified Body certificate under the current MDD, e.g. Class I reusable surgical instruments and devices without intended medical purpose referred to in Annex XVI of the MDR.

WHAT SCOPE WILL SGS BE EXPECTING UNDER THE IVDR?

SGS has also applied for an expanded scope under IVDR to allow for the significant changes in that Regulation, in particular the completely new classification system based upon risk based classification rules. This will mean that a significant proportion of IVD devices that are currently self-certified will now require Notified Body certification under the IVDR.

WHAT DOES THIS MEAN FOR ME AS AN EXISTING SGS CLIENT AND WHAT HAPPENS NEXT?

We will only be in position to propose new contractual documents with our clients once the formal designation under MDR and IVDR is in place, but we will aim to start working with you to determine your business needs and discuss a customized transition plan with each of our customers.

HOW LONG DO I HAVE BEFORE I MUST CHANGE, HOW LONG ARE MY CURRENT CERTIFICATE VALID?

The time until certification under MDR or IVDR is first possible which is dependent upon the progress of the Regulation Implementation and Designation of Notified Bodies. Once this is possible, manufacturers will need to determine their transition strategy and discuss their needs to develop a transition plan with SGS. The earlier that this can be planned will be beneficial to all. The diagram below gives the main dates to consider for certificate validity: (Please see below Figure 1: MDR and IVDR Timeline)

SHOULD I RECALL MY PRODUCT AT THE END OF MY MDD/IVDD CERTIFICATE VALIDITY?

At the end of MDD/IVDD certificate validity (latest 25th of May 2024), devices already placed on the market can continue to be made available until the end of 2025.

WILL I BE ABLE TO HAVE BOTH MDD AND MDR CERTIFICATES? FOR THE SAME DEVICES?

During the transition phase, certificates can be issued under the current MDD and once the MDR requirements such as designated Notified Bodies are in place then potential certificates under MDR may be issued (see another FAQ above). So, you may have some devices that you maintain the MDD certification for until a certain point and others that you will look to get certification under the MDR as soon as this is available. This applies to certification that covers the same devices, there will need to be an ability to clearly distinguish between a device CE marked under the respective Directive or Regulation, e.g. different model numbers or different manufacturing batch numbers if the same model number is used. This will apply equally to IVDR.

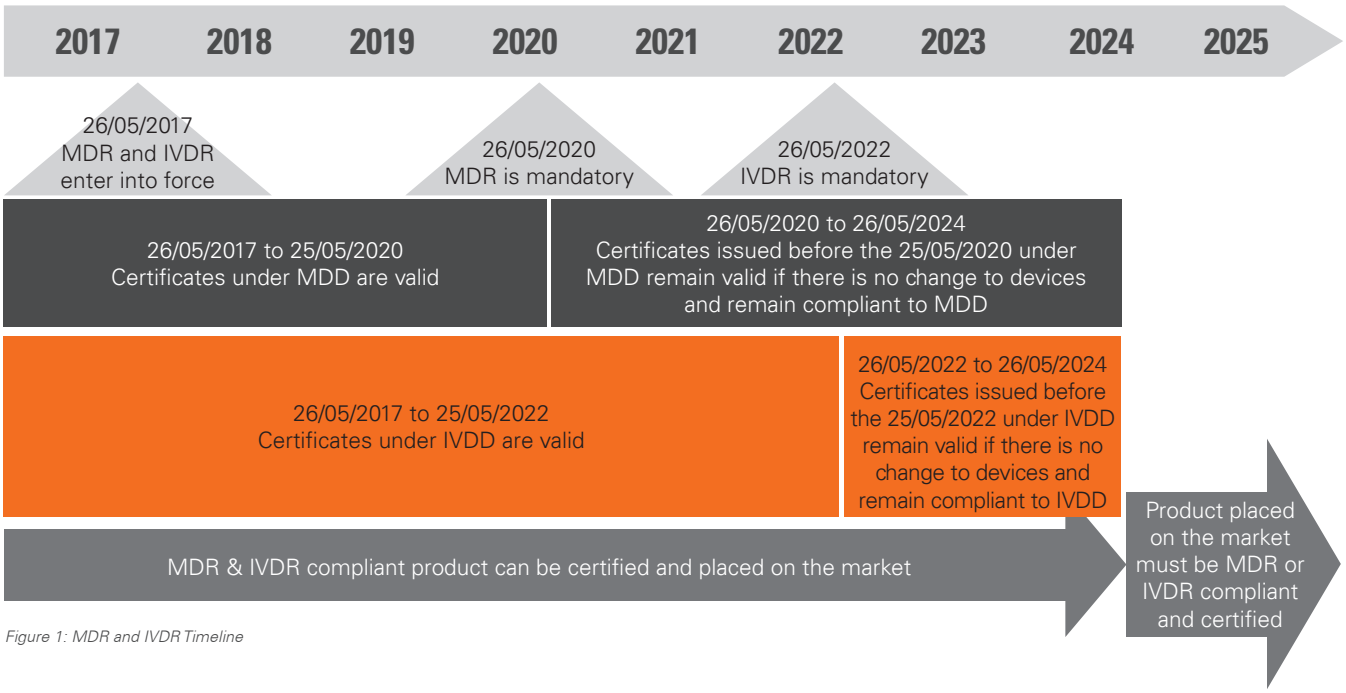

Figure 1: MDR and IVDR Timeline

WILL SGS BE PROVIDING TRAINING ON THE NEW MDR AND IVDR REGULATIONS FOR ITS CUSTOMERS?

SGS is planning to provide new customer training and webinars on the general overview of the MDR and IVDR as well as specific topics in due course, as part of our provision of support to our SGS customers.

MAY I ALREADY ANTICIPATE THE REGULATION REQUIREMENTS AND FORMAT MY TECHNICAL FILE ACCORDING TO REGULATION AND CONTINUE BEING AUDITED IN REGARD TO MDD?

During the transition period you can prepare or update existing technical file according to MDR or IVDR technical file requirement (annex II and III of MDR and IVDR) and be audited in regard to MDD or IVDD.

WILL THE AUDIT UNDER MDR OR IVDR BE DIFFERENT?

Yes, they will. SGS is offering you CE certification based on a 5-year cycle certification including a certification audit followed by at least 4 surveillance audits and at least one unannounced. A new contract between you and SGS will need to be signed as audit time, audit scope and requirements are different for MDR or IVDR than they were for MDD or IVDD.

WHAT ABOUT PRODUCTS NOT CONFORMING WITH MDR OR IVDR AFTER THE TRANSITION PERIOD?

The new requirements will not be enforced retrospectively and products that are not conforming to the MDR or IVDR requirement will not be authorized anymore to be placed on the market.

IF MY PRODUCT DOES NOT CURRENTLY REQUIRE NOTIFIED BODY ASSESSMENT UNDER MDD OR IVDD, BUT WITH THE INTRODUCTION OF THE MDR/IVDR THEY WILL REQUIRE NB CERTIFICATION, IS THERE THE SAME ALLOWANCE TO CONTINUE TO PUT THESE ON THE MARKET UNTIL MAY 2024 WITHOUT BEING AUDITED TO THE MDR/IVDR?

No, if the MDR or IVDR require Notified Body certification (reusable Class I device for example) then your product must conform and have been audited by your Notified Body to MDR or IVDR respectively when the new Regulations come to their final application dates of 26/5/2020 for MDR and 26/5/2022 for IVDR, in order to be placed on the market after these dates.

ABOUT SGS

SGS is the world's leading inspection, verification, testing and certification company. SGS is recognised as the global benchmark for quality and integrity. With more than 95,000 employees, SGS operates a network of over 2,400 offices and laboratories around the world.

We provide competitive advantage, drive sustainability and deliver trust. At SGS, we are continually pushing ourselves to deliver innovative services and solutions that help our customers move their businesses forward.

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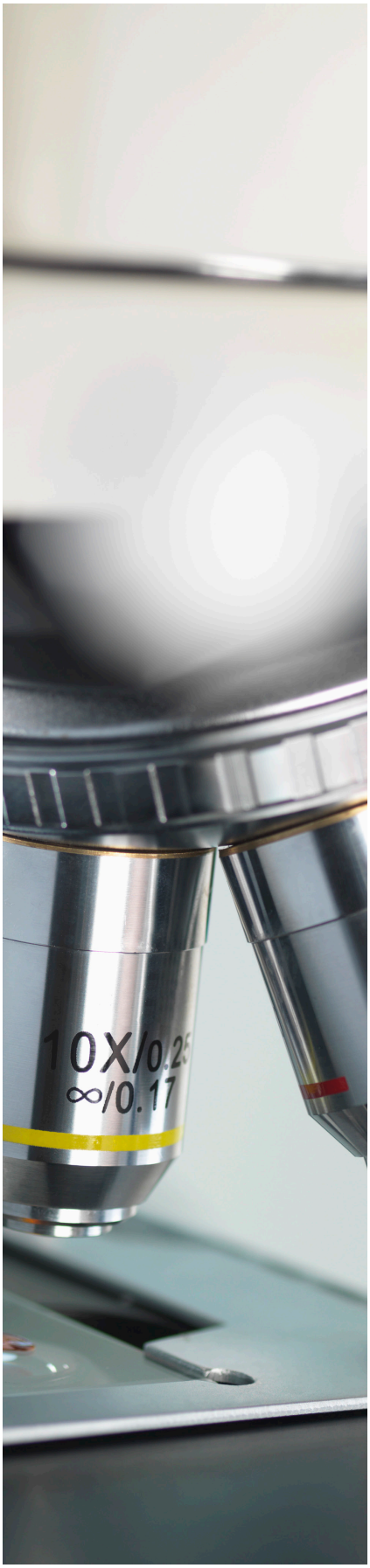

WHEN YOU NEED TO BE SURE