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Start of validity (DoA) of Regulation 2017/745 (MDR) postponed to 26 May 2021

Dear Sir or Madam

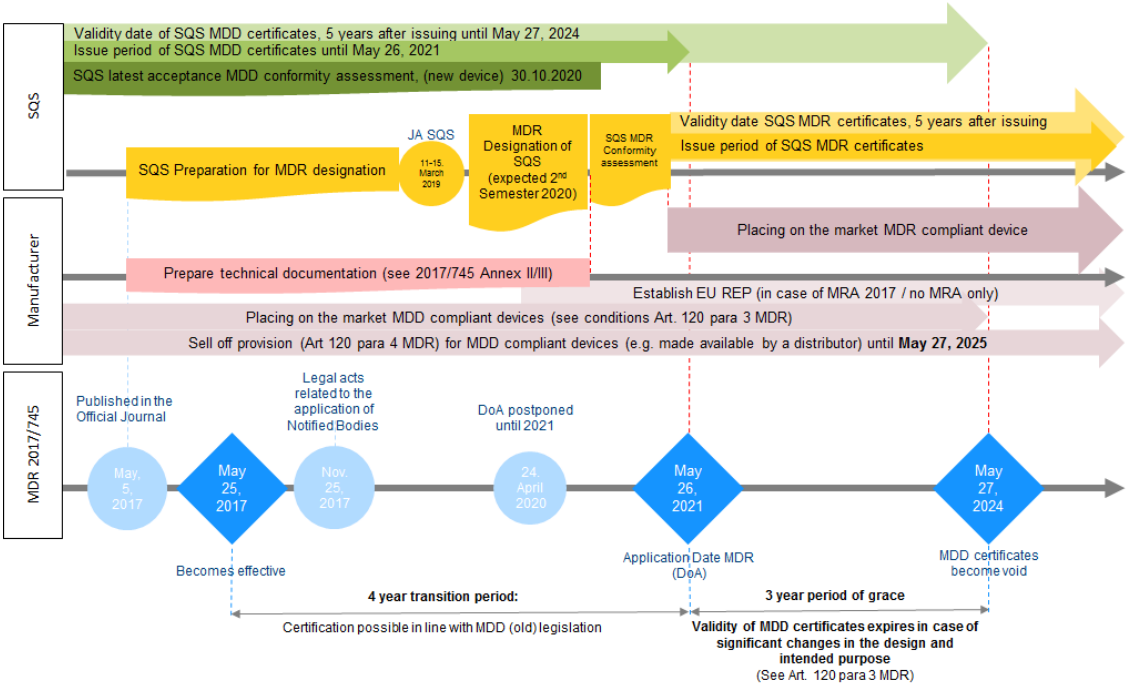
With Regulation (EU) 2020/561, the start of validity (DoA) of Regulation 2017/745 (MDR) was postponed to 26 May 2021 as of 24 April 2020 in order to take account of the current situation with the COVID 19 pandemic and to prevent a shortage of medical devices on the European market. In the following, we would like to inform you about the effects of this postponement and about the status of the SQS designation according to Regulation 2017/745 (MDR).

Status of SQS designation according to Regulation 2017/745 (MDR)

We are working flat out to close the deviations from the Joint Assessment, so that we expect the final report from our national authority, Swissmedic, in the near future. Accordingly, we assume that the designation in accordance with Regulation 2017/745 (MDR) can be granted for SQS in the second half of 2020 and that we will carry out conformity assessments in accordance with Regulation 2017/745 from then on.

Effect of the postponed start of validity (DoA) of Regulation 2017/745 (MDR)

The postponement has various effects we have summarized the points and conclude the following overview:



Period of validity of Swiss legislation (MepV)
With the information dated 16.04.2020, the FOPH announced that Switzerland will join the European solution and postpone the applicability of the revised Swiss medical devices law until 26 May 2021.

MRA CH- EU
The postponement of the applicability of the MDR also means that the provisions on medical devices currently contained in the agreement between Switzerland and the European Community on Mutual Recognition in relation to Conformity Assessment (MRA) will continue to apply beyond 26 May 2020.

Period of validity of Directive 93/42/EEC (incl. IR 920/2013)
The validity of the MDD has been extended by 1 year, and from 26 May 2021 onwards no certificates can be issued under Directive 93/42/EEC.

Duration of the "Period of Grace"
The duration of the "Period of Grace" has been shortened and is now 3 years. During the transitional period (period of grace) from 26 May 2021 - 27 May 2024, you can continue to market (under compliance with all rules according to Art 120 and the continued SQS certification, see also https://www.sqs.ch/en/mdr-assessment) those medical devices that are covered by a valid SQS EC certificate according to Directive 93/42/EEC until 27 May 2024 at the latest.

Continuation of the SQS conformity assessments according to Directive 93/42/EEC
We will now examine new applications for RL 93/42/EEC conformity assessments on a case-by-case basis and, if feasible, accept them until October 1, 2020 so that they are completed before May 26, 2021 if possible. Please note that the examination of the applications will take into account the guarantee of security of supply in the European, but especially the Swiss market. Please also note that SQS may experience capacity bottlenecks at the end of the transition period if many MDD certificates expire there. We therefore encourage you, as far as possible under the current circumstances and compatible with the timetable for the designation of SQS, to maintain your current plans for the transition to MDR. If you have demand, we kindly ask you to contact your SQS auditor at an early stage to arrange the dates.

We look forward to further cooperation with you.

Yours faithfully

Daniel Taddeo
Member of the extended management board