

Media release, 3 August 2021

## **SQS goes to Southern Germany**

*SQS will soon also be represented in Germany. It is investing in a subsidiary in Constance, with which it intends to offer particularly new prospects for SMEs in the European business. The new company will operate primarily as a certification body for medical products.*

For a long time, it was a strategic option, but now the implementation work is already well advanced: The Swiss Association for Quality and Management Systems (SQS) will establish a subsidiary in Constance in September 2021. The new company shall perform a bridging function under its own name. With its services, it will support the export-oriented Swiss economy as well as companies in the European market. A deliberate focus is placed on conformity assessment procedures in the highly regulated medical business. In addition, offers in the area of sustainability will follow, such as the circular economy label Circular Globe.

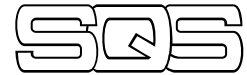
### **Solution for certified medical devices**

«With our subsidiary in the EU, we want to actively support the Swiss MedTech industry, as a certification body, in its European business,» affirms Felix Müller, CEO of SQS. The new base in Germany will enable SQS again to act as a Notified Body for Swiss MedTech companies in the EU area. However, achieving notification as a Conformity Assessment Body for medical devices in accordance with Regulation (EU) 2017/745 – the new Medical Device Regulation (MDR) – is expected to take another year.

This step will ease the consequences of the technical barriers to trade, that have been in place since 26 May 2021, especially for smaller Swiss providers. At that time, both the European MDR and the corresponding revised Swiss Medical Devices Ordinance (MepV) entered into force. However, the additionally necessary update of the Mutual Recognition Agreement (MRA) on Conformity Assessments remains blocked for the time being, as it is linked to the failed negotiations on the Framework Agreement for political reasons.

### **Probably a transitional period for existing certificates**

Whether the MDD certificates issued by SQS under the old jurisdiction will remain recognised throughout the EU until the beginning of 2024 has not yet been conclusively clarified. But it looks good: According to the industry association Swiss MedTech, the EU has recently made a corresponding verbal statement, in positive contrast to the announcement of 26 May 2021. The decisive factor for the change of opinion on the part of the EU is a legal opinion by the law firm Sidley Austin, which was prepared on behalf of the MedTech Europe association. However, the EU's written confirmation that it will recognise SQS's existing MDD certificates for a further two and a half years is still pending. Due to the political summer break in Brussels, this confirmation is not expected before September at the earliest.



### **Details on SQS**

The Swiss Association for Quality and Management Systems (SQS), based in Zollikofen BE, was founded in 1983 as one of the world's first certification bodies. It audits, assesses and certifies organisations and companies in numerous industry sectors. It also offers a wide range of seminars. SQS is constituted as an association and reinvests its profits entirely in its further development. The not-for-profit organisation guarantees neutrality and independence.

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