



Cooperation with Johner Institute

27 July 2021

TÜV SÜD accelerates digitisation in the conformity assessment of medical devices

Munich. The Notified Body at TÜV SÜD Product Service is advancing digital transformation by driving the qualitative expansion of its innovative services in the medtech sector. The testing and certification company plans to offer medical device manufacturers a digital solution for conformity assessment procedures as early as this year. Using the standardised digital solution developed by our cooperation partner, Johner Institute, TÜV SÜD plans to significantly reduce the efforts involved in the submission and review of documentation and thus boost the efficiency and predictability of conformity assessment procedures.

The digitisation solution originates from Johner Institute, which has developed a standardised platform with open interfaces for this purpose. "Manufacturers can now say goodbye to the eminently 20th century procedure of analogue document processing", explains Professor Christian Johner, Head of Johner Institute. "It is a waste of time and effort to copy structured data into unstructured documents and send them to Notified Bodies, which are then faced with extracting the structured data from the unstructured documents. The time is ripe for disruption", says the physicist.

"For manufacturers, freedom from the enormous bureaucracy of the past and being able to embrace the possibility of improving productivity and their international competitive strength have been long overdue", adds Dr Andreas Purde, Global Director Active Medical Devices at TÜV SÜD. In the future, manufacturers can use the new tool to record their technical documentation and provide it directly to TÜV SÜD assessors without first having to convert the content into hard copies. "The new platform supports closer interaction between manufacturers and TÜV SÜD", says Dr Purde in explanation of the digital revolution in conformity assessment that is the company's aim.

The open interfaces on the platform create the basis for a rich ecosystem of a new generation of software tools, giving manufacturers free choice of their Notified Body.

Medical device manufacturers wishing to participate in the upcoming pilot phase of this project are welcome to contact TÜV SÜD (andreas.purde@tuvsud.com) or Johner Institute directly (digitalisierung@johner-institut.de).

About TÜV SÜD Product Service

The activities of TÜV SÜD's Product Service Division focus on ensuring the marketability of consumer, medical and industrial products in global target markets across the entire supply chain. TÜV SÜD is one of the leading Notified Bodies for the conformity assessment of medical devices and is represented by over 900 medical device experts at over 30 locations worldwide. Manufacturers benefit from both TÜV SÜD's technical expertise and its extensive international accreditations and recognitions, including NRTL, INMETRO and the Medical Device Single Audit Program (MDSAP). The advantages are improved access to international markets and shorter time to market.

<https://www.tuvsud.com/en/industries/healthcare-and-medical-devices>

Note for editorial staff: The press release can be downloaded from

<https://www.tuvsud.com/newsroom>.

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