Press release

MDKU is part of the European DIGICAP project to advance digital conformity assessment for medical devices

Erlangen, September 8, 2026. Medical Device Knowledge Units (MDKU) is a consortium partner in the newly launched European DIGICAP project - DIGItalisation of the Conformity Assessment Process - bringing its experience in structured technical documentation and its open-source unified data model for medical devices into a major European initiative for the digitalisation of conformity assessment. DIGICAP is a three-year, €4 million project funded by the European Union's Horizon Europe programme. Coordinated by Team-NB, the European Association of Medical Devices Notified Bodies, the project brings together 19 partners from across Europe, including Notified Bodies, the medical technology industry, research organisations, regulatory and legal experts. The common goal is to move conformity assessment under the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) from today's largely document-centric processes towards a harmonised, machine-readable and interoperable digital framework.

From documents to structured data

Technical documentation for medical devices is still largely created, exchanged and reviewed in the form of documents such as PDFs and spreadsheets. While these documents contain the information required for conformity assessment, the information itself is often unstructured and therefore difficult to process digitally.

This is precisely the challenge MDKU has been addressing since its foundation in 2021. MDKU develops a unified data model that structures the content of technical documentation into individual information units - so-called Knowledge Units - and defines their regulatory meaning and relationships.

The objective is to establish a common regulatory language that enables information to be exchanged and processed independently of individual documents and software systems.

MDKU data model contributes to DIGICAP

Within DIGICAP, MDKU will contribute its existing work and expertise to the development of the project's unified data model for technical documentation.

Building on the work of the MDKU community over the past years and the published DIN SPEC 91509, the data model will contribute to a common European data architecture for the structured exchange of regulatory information between manufacturers, Notified Bodies and other stakeholders.

"When we founded MDKU in 2021, our basic idea was quite simple: if we want to digitalize regulatory processes, we first need to structure the information behind processes and related documents and establish a common language for it. DIGICAP gives us the opportunity to bring the work of the MDKU community into a European collaboration and develop it further together with

manufacturers, Notified Bodies, researchers and other stakeholders.", explained Sarah Panten, Co-Founder and Chair of the Board, MDKU.

Towards an open European ecosystem

DIGICAP aims to develop an open, vendor-neutral framework rather than a proprietary software solution. In addition to a harmonised data architecture, the project will address interoperability standards and APIs, the responsible use of AI and automation, and real-world pilot demonstrations involving manufacturers and Notified Bodies.

For MDKU, this closely aligns with its mission of creating an open foundation for the digitalisation of regulatory processes across the MedTech ecosystem.

DIGICAP will run from 1 September 2026 to 31 August 2029.

About DIGICAP

DIGICAP – DIGItalisation of the Conformity Assessment Process – is a three-year European project funded under the European Union's Horizon Europe research and innovation programme under Grant Agreement No. 101288338. Coordinated by Team-NB, it brings together 19 European partners to advance the digitalisation of medical device and IVD conformity assessment.

More information: **digicap.eu**

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About MDKU e. V.

MDKU e. V. is a non-profit, independent association of experts from the medical technology industry with the aim of advancing the digitalization of regulatory processes through a unified data model. The association's motto, "From the community for the community," underscores the collaborative approach used to solve complex challenges in the development of the data model through a multidisciplinary approach.

The association pursues exclusively non-commercial goals and makes all results openly and freely available to the community in order to enable the widest possible adoption.

Further information: www.mdku.digital

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