

Düsseldorf, August 22, 2023

CUREosity is ISO certified

After a thorough audit, CUREosity GmbH is now ISO certified. The Berlin Cert GmbH has certified CUREosity to have implemented and to apply a quality management system according to the given standards of ISO 13485 as of August 22, 2023. Caesar van Heyningen (Chief Executive Officer): "After the CE certification of the CUREO software, the ISO certification is another milestone for CUREosity. CUREO® as a therapy system convinces users and patients through safety and quality as well as efficient and effective therapy success."

The ISO 13485 standard is an internationally recognized standard for quality management system requirements for developers, manufacturers, and suppliers of medical devices. At CUREosity, these requirements relate to the development, deployment, and distribution of stand-alone software for motor, cognitive and sensory virtual reality therapy, and their purpose is to ensure the quality and safety of products and processes. CUREosity has successfully passed this accreditation process and has been certified according to DIN EN ISO 13485:2021 since August 22, 2023. The certification was carried out by Berlin Cert, a designated testing and certification body for medical devices.

In 2021, CUREO® was initially certified with the CE mark in accordance with the EU Medical Devices Directive (MDD) and then recertified as a medical device in accordance with the European Medical Devices Regulation (MDR) in 2022. These approvals, in addition to the ISO certification that has now been obtained, stand for the fact that product safety and quality have absolute priority at CUREosity and that the specified standards for product and processes are constantly maintained at the highest level.

Dr. Petra Söhnlein, responsible for quality management at CUREosity GmbH, is pleased with the decision of Berlin Cert: "Our priority is to develop safe products for our customers that are and remain consistently state-of-the-art. The specifications of the ISO standard give us clear guidelines to which we align ourselves in order to guarantee this quality and safety in the long term." Caesar van Heyningen also sees further advantages of the certification: "The ISO certificate is also highly regarded and recognized internationally outside the EU. We are therefore pleased that our products will now also be available to many customers in international markets."



ISO test mark for DIN EN ISO 13485:2021



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