

PRESS RELEASE

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Fraunhofer ITEM committed to simplifying the testing and increasing the safety of medical devices in the EU project MDOT

(Hannover/Germany) The aim of the EU project [MDOT](#) is to reduce the burden on med-tech companies: the regulatory requirements they have to meet have increased considerably, since the Medical Device Regulation (MDR) came into force. Funded with 8.3 million euros over a period of five years, a platform shall be developed to support small and medium-sized med-tech companies in the conformity assessment of their medical devices. This will include development of three demonstrator technologies in the fields of inhalers, neural implants, and coatings for hip replacements.

“The aim of MDOT is to prevent a massive loss of innovation and economic strength in the European medical device industry by providing expertise and data through a consortium of medical device stakeholders,” said MDOT coordinator Ulrich Froriep from the Fraunhofer Institute for Toxicology and Experimental Medicine ITEM.

The MDR has introduced a new level of patient safety, product reliability, and clinical performance criteria within the conformity assessment process. This, however, places a heavy burden on medical device innovation in Europe, since the clinical and also the reporting and surveillance requirements have significantly increased. Small and medium-sized enterprises (SMEs) are particularly affected by the extensive documentation and reporting obligations and the new clinical testing requirements of the MDR. To support SMEs and simultaneously enhance quality and regulatory compliance, MDOT will establish a platform enabling automated conformity assessment processes and access to technical and clinical performance data across Europe. Through the MDOT platform, manufacturers can get information about the requirements they have to meet for their conformity assessment, compile the required documentation, and they receive access to state-of-the-art test beds when additional data is required.

In addition to project coordination, Fraunhofer ITEM is mainly involved in the development of a database for the platform, the development of test beds for inhalation technology and accelerated life cycle testing of implants, as well as in biocompatibility testing.

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Representatives of the consortium, which consists of 13 European partners, met in Donostia-San Sebastian (Spain) at the end of August to discuss the project progress and coordinate future developments within MDOT. In addition, the [TBMED](#) and SAFE-N-MEDTECH projects successful in the same funding call presented their approaches, and possible collaboration strategies between all projects were discussed.

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