Diapharm ensures MDR conformity of medical devices: one-stop shop for reassessments of existing products

Münster (DE), 09 September 2020 – Diapharm (www.diapharm.com) is committed to maintaining safe and effective medical devices under the new Medical Devices Regulation (MDR). The company presents an integrated solution for the conformity assessments in accordance with the MDR requirements. Diapharm will be focusing in particular on existing devices whose conformity assessment to date does not comply with the new requirements.

The biggest challenge regarding the MDR conformity of medical devices that have been on the market for a long time is the clinical evaluation. Data submitted under the old Medical Device Directive (MDD) generally does not meet the requirements of the new MDR. However, many companies see a completely new clinical evaluation of their existing medical devices as a risk factor that could potentially endanger the economic viability of these products.

Diapharm has already developed and tested solutions to be able to assess the MDR conformity of such products and to demonstrate clinical, biological and technical equivalence. In addition, the concept developed by Diapharm also takes into account adequate access to the clinical data of the equivalent medical device, which was referenced in literature-based clinical assessments, as required by the regulatory authorities. The concept is in line with the 2020-06 guidelines developed by the EU Commission's Medical Device Coordination Group (MDCG) for the clinical assessment of existing products.

Diapharm Managing Director Dr Thilo Sandner explains: *"Diapharm is able to efficiently provide all the tasks required to ensure MDR conformity from a single source. We offer our clients a one-stop solution consisting of a review of the existing clinical assessment and a validity check of the previous literature references. In the course of this review, we also evaluate potential existing deficits in relation to the MDR requirements. We then work off these deficits point by point in a structured manner – be it through current data from literature, market observations or by collecting new data."*

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For example, the MDCG guidelines explicitly allow for the use of existing clinical assessments as well as existing PMCF studies as a basis for an updated conformity assessment, provided that they allow for a valid conclusion on the safety and efficacy of the product. *"A typical example of insufficient data from literature according to MDR would be a combination product for which clinical data is only available for the individual components but not for the entire formulation. Even in such cases, however, completely new clinical tests may not be necessary. Depending on the specific case, one could draw on additional data collected in vitro to prove that the product retains its efficacy and safety in combination,"* says Dr Guido Middeler. Market participants with comparable medical devices might also benefit from synergy effects of possible *shared studies* in which the assessed product is equivalent to their respective own product.

As of 26 May 2021, all medical devices placed on the market in accordance with MDD requirements in the past must comply with the deviating MDR requirements and provide the necessary proof. The transition phase for existing products will expire between May 2021 and May 2024, depending on certain product conditions, such as the validity of the current MDD certificates.

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Caption (Middeler-Dr-Guido-DIAPHARM.jpg)
Clinical tests are not always necessary to attain MDR conformity, says Diapharm's Dr. Guido Middeler.

Background information: Diapharm GmbH & Co. KG
Diapharm (www.diapharm.com) is a leading global service provider and consulting firm for the consumer healthcare and pharmaceutical industry. With around 100 employees at seven locations in Germany, the Netherlands, Austria and China, Diapharm provides consulting services to clients in strategic matters, assumes responsibility for regulatory, medical and scientific tasks, as well as for quality assurance. Diapharm supports manufacturers and distributors of medicinal products, medical devices and healthcare products throughout the world.