Handling Brexit:
Diapharm sets up UK branch for medical devices

London (UK), Münster, Lübeck (DE), 22 December 2020 – To give manufacturers of medical devices continued access to the British market after Brexit, the consultancy and service provider Diapharm is establishing a new branch in the UK effective 1 January 2021. From there, Diapharm will act as a UK Authorised Representative for clients from the European Union and ensure cooperation with the authority responsible for approvals in the UK, the Medicines and Healthcare Products Regulatory Agency (MHRA).

The move will give companies from the European Union a way to satisfy the new rules for medical devices in the UK, which will require all products to be registered with the MHRA from 1 January 2021. This registration will be open only to companies based in the UK.

“This UK representative service is the logical next step in expanding our portfolio,” says Dr Guido Middeler, who heads the Medical Devices team at Diapharm. “For years, our EU representative service for market entry in the European Union has been a fixed point of contact for the international healthcare industry.”

Diapharm’s knowledge of the market and specialist expertise will also benefit manufacturers of borderline products that want to keep their products on the British market, as the regulatory status of all healthcare products is to be reassessed by the MHRA as part of the registration process. Middeler explains: “A different or dissenting assessment by the MHRA can jeopardise a product’s marketability. Diapharm helps pharmaceutical companies to make a solid case for classification in the desired marketability segment by providing the justification to clear up any borderline issues.”

In addition to providing strategic advice and acting as a UK Authorised Representative, Diapharm will also make it possible for European manufacturers of medical devices and in vitro diagnostics to obtain a conformity assessment from a notified body in the UK. With existing EU certificates set to become invalid in the UK by June 2023, companies will need

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the support of a responsible person based in Britain after this deadline to be able to apply for the relevant UK certificates.

The UK branch allows Diapharm to take on the role of responsible person for clients within and outside the UK and safeguard the marketability of medical devices for the British market.

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Caption *(Middeler-Dr-Guido-DIAPHARM.jpg)*
Diapharm's Dr Guido Middeler offers medical devices manufacturers a UK representative service.

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 in Europe, 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.