# Diapharm certified as a European Authorised Representative for medical devices from third states

**Lübeck (Germany), 19 March 2019 –** In addition to its certification for the development, production, final inspection and marketing of medical devices, the pharmaceutical service provider Diapharm (www.diapharm.com) has now also been EN ISO 13485:2016 certified as a European Authorised Representative (EAR or EC REP).[1] European law requires companies based outside the EU that want to market their products in the European single market to appoint an EC REP. Demand for this EAR function has risen dramatically, due in no small part to many companies' Brexit preparations, as Dr Guido Middeler, Partner and Head of Medical Devices at Diapharm, explains. In all remaining potential Brexit scenarios, the United Kingdom will ultimately become a third state for the remaining EU member countries.

The EC REP must be indicated on a product's packaging. He or she represents the medical device manufacturer in its dealings with the authorities and bears third-party liability for the use of the products. Part of this duty includes appointing a safety officer. Diapharm takes on this responsibility on manufacturers' behalf.

"Our services as an EC REP can also go beyond the regulatory requirements," Diapharm General Manager Ralf Sibbing adds. "Diapharm's years of experience and certified quality management systems enable it to take on a very wide range of responsibilities, from acting as an EC REP to playing the legal role of manufacturer." As a result, non-European medical device manufacturers can choose whether they want to outsource full manufacturer responsibility for their products to the pharmaceutical service provider or allow Diapharm to represent them in their dealings with the European authorities.

*(approx. 2,000 characters)*

**Contact:**
**Diapharm GmbH & Co. KG**
Hafenweg 18-20
48155 Münster, Germany

Contact person:
Nicole Sibbing

Phone: +49 (0)251 - 60935-517
nicole.sibbing@diapharm.de
www.diapharm.com

**Agency contact:**
co-operate Wegener & Rieke GmbH
Zumsandestrasse 32
48145 Münster, Germany

Contact person:
Christian Rieke

Phone: +49 (0)251 - 3222611
wort@co-operate.net
www.co-operate.net

[1] Re-certification scheduled for July 2019

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**Photo (Middeler_Dr_Guido_DIAPHARM.jpg)**

European Authorised Representative for medical devices: Diapharm Partner 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.*

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