EU Certificate according to Article 16 Regulation (EU) 2017/746

We hereby certify the company

kohlpharma GmbH
Im Holzhau 8
66663 Merzig
Germany

the introduction and application of a quality management system in accordance with Article 16 (3) of Regulation (EU) 2017/746.

An audit by mdc has proven that this quality management system meets the following requirements:

Article 16(3) of Regulation (EU) 2017/746

of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Surveillance is carried out by annual audits.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered by this certificate as well as further information and conditions are contained on the following pages.

Valid from	2023-09-27	Registration No.	D1487100004
Valid until	2028-09-26	Report No.	P23-00620-267645

Stuttgart, 2023-09-27

Head of Notified Body

Activities according to Article 16 (2) of Regulation (EU) 2017/746 covered by this certificate and associated product types:

a) Provision, including translation, of the information to be provided by the manufacturer, in accordance with Section 20 of Annex I

IVR 0602	Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

b) Changes to the outer packaging of a device already placed on the market, including a change of pack size

IVR 0602	Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease