

EU Certificate

acc. to Art. 16 (4) Regulation (EU) 2017/745

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company:

kohlpharma GmbH

Im Holzhau 8
66663 Merzig
Germany

has implemented and applies a quality management system in accordance with Article 16 (3) of Regulation (EU) 2017/745 to carry out the activities referred to on the following page for the listed product types.

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

Article 16 (3) of Regulation (EU) 2017/745

of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Section 3 of Annex IX to Regulation (EU) 2017/745.

This certificate consists of 2 pages. Details of the activities and product types affected by this certificate are included on the following pages.

Valid from:	2023-09-27	Registration No.	D1487100005
Valid until:	2027-06-09	Report No.	P23-00620-267036

Stuttgart, 2023-09-27

A blue ink signature, appearing to be 'MLC', is written over the text 'Head of Notified Body'.

Head of Notified Body

Activities and product types covered by this certificate:

(a) Provision, including translation, of the information to be provided by the manufacturer, in accordance with Section 23 of Annex I

MDN 1102	Non-active osteo- and orthopaedic implants
MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1204	Non-active non-implantable devices for wound and skin care
MDN 1206	Non-active non-implantable ophthalmologic devices
MDN 1208	Non-active non-implantable instruments
MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing

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

MDN 1202	Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis
MDN 1204	Non-active non-implantable devices for wound and skin care
MDN 1206	Non-active non-implantable ophthalmologic devices
MDN 1208	Non-active non-implantable instruments
MDN 1211	Non-active non-implantable devices for disinfecting, cleaning and rinsing