For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

ANTITOXIN GmbH
Industriestraße 88
69245 Bammental
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/746 for conformity assessment.

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

Annex IX – Chapter I (Quality Management System)

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 in accordance with Annex IX, Section 3 of Regulation (EU) 2017/746.

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

Valid from	2026-05-22	Registration No.	D1052200101
Valid until	2029-03-17	Report No.	P25-01124-361226

Stuttgart, 2026-05-22

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-098

Devices:

Devices intended to be used for blood grouping to ensure the immunological compatibility of blood, blood components, cells that are intended for transfusion (Kell-System)

Risk class: D

Agglutination test devices intended to be used for blood grouping

Risk class: C
W0103 HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests

Notes:

For class A devices placed on the market in sterile condition the involvement of mdc is limited to the assessment of the aspects of manufacture concerned with securing and maintaining sterile conditions.

For devices for self-testing and near-patient testing the involvement of mdc additionally refers to the assessment of aspects according to Annex IX, Section 5.1.

For the placing on the market of class D devices an EU technical documentation assessment certificate is also required.

The certificate is based on the previous certificate

D1052200089 (2024-03-18)
D1052200092 (2024-08-14)

with the following changes to D1052200092:
New product in already certified product group (IVP 3001 / W0103): IVT 2009 added to scope