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	2024-08-16	Registration No.	D1052200092
Valid until	2029-03-17	Report No.	P23-01453-306333

Stuttgart, 2024-08-14

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
W01030000 HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY
IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests

Notes:

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)

with the following changes to D1052200089:
Supplemented with the product group "Agglutination test devices intended to be used for blood grouping"