

VDE Testing and Certification Institute

A member of VDE e.V. · Accredited by DAkkS

Merianstraße 28 · 63069 Offenbach am Main · Germany

DAKKS ACCREDITATION

D-PL-19050-01-00

ISO/IEC 17025:2017

CERTIFICATE OF COMPLIANCE

Electrical Safety Testing — IVD Medical Equipment

Certificate No.: VDE-CERT-2024-EN61010-03342

This is to certify that the equipment described herein has been tested and found to comply with the requirements of:

EN 61010-2-101:2017

Safety requirements for electrical equipment for measurement, control, and laboratory use —
Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

as supplemented by the general requirements of EN 61010-1:2010+A1:2019, applied to the following equipment:

Blood Gas Analyzer BGA-500

Manufacturer: RegMed Diagnostics GmbH · Grünwalder Weg 28, 82041 Oberhaching, Germany

Model / Type Reference: BGA-500

Test Report Reference: VDE-TR-2024-EN61010-08821

Rated Supply: 100–240 V AC, 50/60 Hz, 85 W max · Protection Class I

Intended Use: IVD medical equipment for clinical laboratory — Blood Gas Analysis

TEST PERIOD

03 Jun – 28 Jun 2024

DATE OF ISSUE

10 July 2024

VALID UNTIL

09 July 2027

Dr. Klaus Zimmermann
Head of Electrical Safety Division
VDE Testing and Certification Institute

VDE
Tested for Safety

This certificate is issued on the basis of test report VDE-TR-2024-EN61010-08821 and is valid only for the equipment described herein.
This certificate does not imply or guarantee that all production units will conform to these requirements. It remains the property of VDE Testing and Certification Institute.

Verification: www.vde.com/certificatecheck · DAkkS: www.dakks.de

SPECIMEN