

VDE Testing and Certification Institute

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TEST REPORT

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

Blood Gas Analyzer BGA-500

Manufacturer: RegMed Diagnostics GmbH · Model: BGA-500 · Serial: PROTO-2024-001

REPORT NUMBER

VDE-TR-2024-EN61010-08821

TEST STANDARD

EN 61010-2-101:2017

TEST START DATE

03 June 2024

TEST END DATE

28 June 2024

APPLICANT

RegMed Diagnostics GmbH

OVERALL RESULT

PASS ✓

1. SCOPE & PURPOSE

This test report documents the evaluation of the Blood Gas Analyzer BGA-500 against the requirements of EN 61010-2-101:2017, which specifies particular safety requirements for IVD medical equipment. The testing was conducted to support the CE marking process under Regulation (EU) 2017/745 (MDR).

EN 61010-2-101 is the applicable collateral/particular standard for IVD equipment and supplements the general requirements of EN 61010-1:2010+A1:2019. Where EN 61010-2-101 is silent, the requirements of EN 61010-1 apply.

2. SAMPLE INFORMATION

Parameter	Detail
Product Name	Blood Gas Analyzer BGA-500
Manufacturer	RegMed Diagnostics GmbH, Grünwalder Weg 28, 82041 Oberhaching, Germany
Model / Type Reference	BGA-500
Serial Number (Test Sample)	PROTO-2024-001
Hardware Version	HW Rev. 3.1
Software Version	SW v2.4.1
Rated Voltage	100–240 V AC, 50/60 Hz
Rated Power	85 W (max)
Protection Class	Class I (Earth Protected)
IP Rating	IPX0 (no ingress protection)
Intended Use Environment	Indoor laboratory / clinical use, Pollution Degree 2

3. TEST CONDITIONS

Ambient Temperature: 23°C ± 2°C | **Relative Humidity:** 45–65% RH | **Atmospheric Pressure:** 860–1060 hPa

Referenced Standards: EN 61010-1:2010+A1:2019 (General requirements) · EN 61010-2-101:2017 (IVD particular requirements) · EN 61326-2-6:2013 (EMC for IVD) · EN ISO 14971:2019 (Risk management) · IEC 61010-031:2015+A1:2019 (Hand-held probe assemblies)

4. TEST PERSONNEL

Role	Name	Qualification
Lead Test Engineer	Dipl.-Ing. Thomas Berger	Certified IEC 61010 Test Specialist, 12 years exp.
Assistant Engineer	M.Sc. Anika Hoffmann	IVD Safety Testing, VDE Certified
Technical Reviewer	Dr. Klaus Zimmermann	Head of Electrical Safety, VDE Institute

5. TEST RESULTS SUMMARY

Clause	Requirement	Test Method	Result
4.4.2	Protection against electric shock — Touch current	Measurement per EN 61010-1 cl.6.4	PASS
6.1	Protection against electric shock — Basic insulation	Hi-pot 1500 V AC, 1 min	PASS
6.3	Protective earth continuity	$\leq 0.1 \Omega$ between PE and accessible metal parts	PASS
6.5	Clearances and creepage distances	Visual + measurement per Table 6	PASS
7.1	Marking and documentation	Document review, label inspection	PASS
9.1	Mechanical hazards — Stability	Tilt test 10°	PASS
9.3	Moving parts — Accessibility	Probe guard inspection	PASS
10.1	Radiation hazards — Optical	Laser / LED emission check	PASS
11.1	Temperature limits — Accessible surfaces	Thermocouple measurement under normal load	PASS
11.3	Abnormal operation — Overload	Single fault condition test	PASS
13.1	Hazardous substances — Reagents containment	Leakage simulation test	PASS
13.2 (IVD)	Biohazard — Aerosol containment	Fluorescent tracer aerosol test	PASS
13.3 (IVD)	Reagent spillage — Electrical safety	Simulated spillage, insulation re-check	PASS
14.1	Software / Firmware safety class	Risk class determination per IEC 62304	PASS
14.4	Alarm system — Audible/visual	Functional alarm trigger test	PASS

6. CONCLUSION

✓ COMPLIANT — OVERALL RESULT: PASS

The Blood Gas Analyzer BGA-500, manufactured by RegMed Diagnostics GmbH, has been tested and found to comply with the requirements of **EN 61010-2-101:2017** and the applicable clauses of EN 61010-1:2010+A1:2019 relevant to IVD medical equipment.

All 15 test clauses evaluated resulted in a PASS verdict. No non-conformities were identified during testing.

Dipl.-Ing. Thomas Berger
Lead Test Engineer
VDE Testing and Certification Institute

Dr. Klaus Zimmermann
Technical Reviewer & Approver
VDE Testing and Certification Institute

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