

BSI Group The Netherlands B.V.

Notified Body under Regulation (EU) 2017/745
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Notified Body No.: **2797**
Registered in NANDO (EU Commission)



EC CERTIFICATE

Issued pursuant to Regulation (EU) 2017/745 on Medical Devices (MDR)

Certificate No.: **CE-MDR-2797-2024-00341** |

Annex IX — EU-Type Examination

MANUFACTURER

Company Name: **RegMed Diagnostics GmbH**
Address: **Grünwalder Weg 28, 82041 Oberhaching, Germany**
EUDAMED SRN: **DE-MF-000123456**

DEVICE INFORMATION

Device Name: **Blood Gas Analyzer Model BGA-500**
Classification: **Class IIb — Rule 10: In vitro diagnostic device for measurement of blood gases**
Basic UDI-DI: **(01)04015678901234**
Intended Purpose: **Quantitative determination of pH, pCO₂, pO₂, electrolytes and metabolites in whole blood for clinical diagnosis**

APPLICABLE STANDARDS

- ISO 15189:2022 — Medical laboratories: Requirements for quality and competence
- EN ISO 14971:2019 — Application of risk management to medical devices
- IEC 62353:2014 — Medical electrical equipment: Recurrent test and test after repair
- EN ISO 11135:2014 — Sterilization of health-care products (where applicable)
- EN ISO 10993-1:2018 — Biological evaluation of medical devices

DATE OF ISSUE
01 June 2024

VALID FROM
01 June 2024

VALID UNTIL
31 May 2029

Sarah van den Berg
Technical Manager, Notified Body Operations
BSI Group The Netherlands B.V.

BSI

Important Notes:

- This certificate is valid only when accompanied by the current schedule of devices and the applicable technical documentation.
- This certificate is subject to satisfactory results of annual surveillance audits as required under Regulation (EU) 2017/745.
- The manufacturer must notify BSI Group of any planned changes to the certified device in accordance with MDR Article 54.
- This certificate may be verified at ec.europa.eu/growth/tools-databases/nando

SPECIMEN