Deniz Biyokimya

SHD
SCIENCE HEALTH DIAGNOSTICS

# INNOVIQURE

## Chemiluminescence Immunoassay Systems

One reagent platform. Two throughputs.
248 assays.

**NEXUS · SPECTRUM**




### NEXUS

120 tests / hour

### SPECTRUM

200 tests / hour

**120 → 200**

**tests per hour**

two throughputs, one platform

**248**

**assays**

from thyroid to full autoimmune panels

**2–8 °C**

**on board**

24-hour uninterrupted reagent cooling

**Deniz Biyokimya Ürünleri Dış Ticaret Anonim Şirketi**

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In vitro diagnostic medical devices · Designed and manufactured in Türkiye

DB/BRO/INNOVIQURE/2026-001 · November 2026

# One platform, two throughputs

The INNOVIQURE series is a family of fully automated, random-access chemiluminescence immunoassay analyzers built around a single reagent platform. NEXUS and SPECTRUM run the same reagent kits, the same calibrators and controls and the same consumables. A laboratory can therefore move from 120 to 200 tests per hour, or run both instruments side by side, without changing methods, retraining staff or revalidating its menu.

### One reagent platform across the series

Identical reagent kits, calibrators, controls and consumables on both analyzers. Adding capacity does not mean adding a second inventory, a second set of application data or a second training programme.

### Direct chemiluminescence on paramagnetic particles

The assay is based on the direct chemiluminescence reaction of an acridinium ester, using paramagnetic particles as the solid phase. Quantitative assays are calibrated by four-parameter logistic curve fitting (4PLC); qualitative assays are reported as a cut-off index (COI).

### Continuous random access with STAT priority

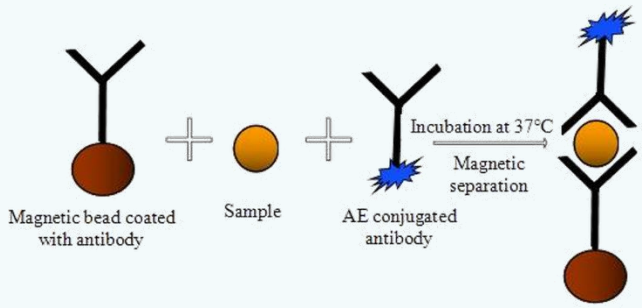
Batch, random and STAT modes are available. A dedicated STAT channel accepts an emergency sample at any time, without interrupting the run in progress.

### Built for the routine laboratory

Twenty-four hour uninterrupted on-board reagent refrigeration at 2–8 °C, disposable assay cups, clot and liquid-level detection, and connection to the laboratory information system over the network.

## How the assay is measured

Paramagnetic particles carry the immune reaction. The direct chemiluminescence reaction of an acridinium ester, released by the Pre-Trigger and Trigger solutions, produces photons whose intensity is proportional to the concentration in the sample within the detection range. Three assay formats are supported.




*Two-site sandwich format, incubation at 37 °C followed by magnetic separation*

Two further formats are supported. In the competitive format the analyte in the sample and an acridinium ester-conjugated antigen compete for a limited number of antibody sites on the bead. In the antibody capture format a coated bead captures the antibody present in the sample, and an acridinium ester-conjugated antibody is then bound; incubation at 37 °C is followed by magnetic separation and washing.

## At a glance

| | INNOVIQURE NEXUS | INNOVIQURE SPECTRUM |
|---|---|---|
| Throughput | **120 tests / hour (max)** | **200 tests / hour (max)** |
| Sample positions | **30** | **60 (6 racks × 10)** |
| Reagent positions | **10** | **25** |
| Dimensions W × D × H | **430 × 680 × 620 mm** | **1000 × 670 × 640 mm** |
| Net weight | **62 kg** | **129 kg** |

# INNOVIQURE NEXUS

## Chemiluminescence Immunoassay Analyzer

A compact bench-top analyzer for the laboratory that needs a full immunoassay menu in a small footprint: 430 mm wide, 62 kg, and a first result in ten minutes.



| 120 | ≤ 10 | 30 | 10 |
|---|---|---|---|
| **tests / hour** | **minutes** | **positions** | **positions** |
| maximum throughput | time to first result | samples, calibrators, controls | refrigerated reagent disk |

### Sample and reagent loading

A one-piece disc structure with 30 sample positions and 10 reagent positions. The reagent disk holds 2–8 °C refrigeration twenty-four hours a day, without interruption. A STAT channel takes an emergency sample at any time. The split reagent cover means only the small lid is opened when a kit is changed.

### Reaction and washing

The reaction disk is held within ±0.3 °C of the set value, with a fluctuation below 0.2 °C. An intelligent magnetic-field design governs separation and washing.

### Assay cup handling

A hopper carrying more than 200 disposable assay cups, with automatic sorting, loading and allocation. The three-axis gripper raises an alarm on collision and on a failed cup grab.

### Single sample / reagent probe

One stainless-steel probe for both sample and reagent, which reduces the maintenance burden. The probe is washed inside and outside at a vacuum wash pool. Clot detection, liquid-level detection and anti-collision protection in both the horizontal and the vertical axis.

### Non-contact mixing

High-speed vortex mixing. The mixer never touches the reaction mixture, so there is no contamination path through the mixing step.

### Operation

15-inch colour LED touch screen; neither mouse nor keyboard is required. Consumables are managed in real time and can be added or replaced at any point in a run. Alarms are classified so that the run in progress is completed wherever it safely can be.

Bench footprint 430 × 680 × 620 mm (W × D × H) · net weight 62 kg · minimum bench load-bearing capacity 200 kg · input power 850 VA

# INNOVIQURE SPECTRUM

## Chemiluminescence Immunoassay Analyzer

The high-throughput member of the series: sixty sample positions on removable racks loaded during operation, and twenty-five refrigerated reagent positions, for laboratories running long, uninterrupted sessions.



| 200 | 60 | 25 | 129 |
|---|---|---|---|
| **tests / hour** | **positions** | **positions** | **kg** |
| maximum throughput | 6 racks × 10 samples | refrigerated reagent disk | net weight |

### Continuous sample loading

Sixty sample positions on six removable racks of ten. Racks are loaded into free positions while the system is running, and new samples are read and scheduled automatically without stopping the run. Adapters accept a range of primary tube types; a STAT channel takes an emergency sample at any time.

### Twenty-five reagent positions

A disc-type reagent disk with twenty-five positions, refrigerated at 2–8 °C around the clock. Vial caps close automatically between pipetting steps, so a full working menu stays on board without evaporation loss.

### Single sample / reagent probe

One stainless-steel probe for both sample and reagent, washed at a vacuum wash pool. Every aspiration is checked for clots; a clotted sample is rejected and flagged, never reported. Liquid-level and anti-collision protection in both axes.

### Reaction and washing

The reaction disk is held within ±0.3 °C of the set value, with a fluctuation below 0.2 °C. An intelligent magnetic-field design governs separation and washing.

### Non-contact mixing and cup handling

High-speed vortex mixing without contact. Disposable assay cups are sorted, loaded and allocated automatically; the gripper raises an alarm on collision and on a failed cup grab.

### Operation and connectivity

15-inch colour LED touch screen. Reagent packs and primary sample tubes are both read by the on-board barcode reader, and results outside the measuring range are rerun automatically without operator intervention. Three USB ports and one LAN port; results are exchanged with the laboratory information system over the network.

Bench footprint 1000 × 670 × 640 mm (W × D × H) · net weight 129 kg · minimum bench load-bearing capacity 200 kg · input power 1000 VA

# Technical specifications

| | NEXUS | SPECTRUM |
|---|---|---|
| **SYSTEM** | | |
| System | Fully automated, random-access chemiluminescence immunoassay analyzer | |
| Degree of automation | Automatic | |
| Measuring principle | Direct chemiluminescence of an acridinium ester, with paramagnetic particles as the solid phase | |
| Result calculation | Quantitative: four-parameter logistic curve fitting (4PLC). Qualitative: cut-off index (COI) | |
| Automatic rerun | | **Out-of-range results** |
| Software full version | V1.2.11 | V1.2.101074 |
| **THROUGHPUT AND CAPACITY** | | |
| Throughput | 120 tests / hour (max) | 200 tests / hour (max) |
| Time to first result | ≤ 10 minutes | — |
| Sample positions | 30 | 60 (6 racks × 10) |
| Sample loading | | **Continuous, during operation** |
| Reagent positions | 10 | 25 |
| Reagent refrigeration | 2–8 °C, 24 h uninterrupted, on the reagent disk | |
| Reagent evaporation control | | **Automatic cap closure** |
| Assay cup | Disposable | |
| Sample types | Human serum, plasma, whole blood and urine | |
| Sample integrity | | **Clot detection and rejection** |
| **ANALYTICAL PERFORMANCE** | | |
| Sample dispensing accuracy and repeatability | 10 µL — bias ≤ ±5 %, CV ≤ 2 %  200 µL — bias ≤ ±3 %, CV ≤ 1 % | |
| Reaction disk temperature | Within ±0.3 °C of the set value, fluctuation below 0.2 °C | |
| Linear correlation | r ≥ 0.99 over a concentration range of not less than three orders of magnitude | |
| Repeatability of luminescence value | CV ≤ 5 % with chemiluminescent reagents | |
| Stability of luminescence value | Variation ≤ ±10 % with chemiluminescent reagents | |
| Carry-over rate | ≤ $5 \times 10^{-6}$ | |
| Intra-batch precision, clinical test | ≤ 8 % CV | |

| | NEXUS | SPECTRUM |
|---|---|---|
| **PHYSICAL AND ELECTRICAL** | | |
| Dimensions W × D × H | 430 × 680 × 620 mm | 1000 × 670 × 640 mm |
| Net weight | 62 kg | 129 kg |
| Heaviest modules | Reagent processing module 15 kg · reaction module 20 kg | |
| Power supply | 100–240 V~, 50/60 Hz | |
| Input power | 850 VA | 1000 VA |
| Fuse | F6.3L250V | |
| Workbench | Minimum load-bearing capacity 200 kg, inclination less than 1/200, flat and vibration-free | |
| **ENVIRONMENT** | | |
| Operating temperature | 10 °C to 30 °C | |
| Operating humidity | ≤ 85 % RH, no condensation | |
| Atmospheric pressure | 61.60 kPa to 106.0 kPa | |
| Altitude | ≤ 4000 m | |
| Storage and transport | −20 °C to +55 °C, humidity ≤ 93 % | |
| **CONTROL UNIT AND INTERFACES** | | |
| Control unit | RAM 2 GB or above, memory 8 GB or above, operating system Linux 4.1 or above | |
| Display | 15-inch colour LED touch screen | |
| Interfaces | USB 2.0, Ethernet RJ45, barcode scanner port | 3 × USB, 1 × LAN, 1 × barcode scanner port |
| Barcode reading | | **Reagents and samples** |
| Host communication | Bidirectional exchange with the laboratory information system (LIS) over the network | |
| **STANDARDS APPLIED** | | |
| Electrical safety | EN 61010-1 · EN 61010-2-101 | |
| Electromagnetic compatibility | EN 61326-1 · EN 61326-2-6 · EN 55011 Group 1 Class A | |
| Quality management and risk | EN ISO 13485 · EN ISO 14971 · EN ISO 18113-3 | |

*A value that spans both columns applies to both analyzers. A value shown only under SPECTRUM is specified for that analyzer. Specifications are subject to change without notice.*

# Assay menu

Endocrinology, cardiac, oncology, infectious disease and organ function

## THYROID

Thyroid Stimulating Hormone (TSH)
Total T3 (TT3 / T3)
Total T4 (TT4 / T4)
Free T3 (FT3)
Free T4 (FT4)
Anti-Thyroid Peroxidase (Anti-TPO / TPOAb)
Anti-Thyroglobulin (Anti-TG / TGAb)
Thyroglobulin (Tg / TG)
T-Uptake
Reverse T3 (rT3)
TSH Receptor Antibody (TRAb / TSHR)

## REPRODUCTIVE AND FERTILITY

Beta-hCG (β-hCG / Total β-hCG)
Testosterone (TESTO)
Progesterone (PROG)
Follicle Stimulating Hormone (FSH)
Luteinizing Hormone (LH)
Estradiol (E2)
Anti-Müllerian Hormone (AMH)
DHEA-Sulfate (DHEA-S)
Prolactin (PRL)
Sex Hormone Binding Globulin (SHBG)
Inhibin B
Pregnancy-Associated Plasma Protein-A (PAPP-A)
Unconjugated Estriol (uE3)

## ADRENAL, PITUITARY AND GROWTH

Cortisol
Adrenocorticotropic Hormone (ACTH)
Aldosterone
IGF-1
Renin

## DIABETES

Insulin (INS)
C-Peptide (C-P)
Anti-GAD (Glutamic Acid Decarboxylase) IgG
Anti-IA2 IgG
Anti-Insulin IgG
Anti-Islet Cell IgG
Anti-ZnT8 IgG

## ANAEMIA

Vitamin B12
Folate (Folic Acid)
Ferritin
EPO
Anti-Intrinsic Factor (Anti-IF) IgG
Anti-Parietal Cell (Anti-PCA) IgG

## BONE METABOLISM

Growth Hormone (hGH)
25-OH Vitamin D (Total)
Parathyroid Hormone (PTH / intact PTH)
Osteocalcin (OC)
Calcitonin (CT)

## CARDIAC

Troponin I (hs-cTnI / cTnI)
Myoglobin (Myo)
CK-MB (mass)
D-Dimer
NT-proBNP
Digoxin
Digitoxin
Heart-type Fatty Acid Binding Protein (H-FABP)
Lipoprotein-associated Phospholipase A2 (Lp-PLA2)
S100-β Protein
ST2 (Suppression of Tumorigenicity 2)
Troponin T (hs-cTnT / cTnT)

## THROMBOSIS AND COAGULATION

Fibrin/Fibrinogen Degradation Products (FDP)
Plasmin-α2 Antiplasmin Inhibitor Complex (PIC)
Thrombin-Antithrombin Complex (TAT)
Thrombomodulin (TM)
Tissue Plasminogen Activator-Inhibitor Complex (t-PAIC)

## INFLAMMATION AND SEPSIS

Procalcitonin (PCT)
C-Reactive Protein (CRP / hs-CRP / W-CRP)
Heparin Binding Protein (HBP)
Serum Amyloid A (SAA)

## CYTOKINES AND INTERLEUKINS

Interleukin-10 (IL-10)
Interleukin-12 P70 (IL-12P70)
Interleukin-17A (IL-17A)
Interleukin-1β (IL-1β)
Interleukin-2 (IL-2)
Interleukin-2 Receptor (IL-2R)
Interleukin-4 (IL-4)
Interleukin-5 (IL-5)
Interleukin-6 (IL-6)
Interleukin-8 (IL-8)
Tumor Necrosis Factor-α (TNF-α)

## TUMOUR MARKERS

Pro-Gastrin Releasing Peptide (ProGRP)
Alpha-Fetoprotein (AFP)
Carcinoembryonic Antigen (CEA)
Total PSA (t-PSA)
Free PSA
CA 125
CA 19-9
CA 15-3
CA 72-4
CYFRA 21-1
Human Epididymis Protein 4 (HE4)
Neuron Specific Enolase (NSE)
Beta-2 Microglobulin (β2-MG)
CA 242
CA 50
PIVKA-II (DCP)
Squamous Cell Carcinoma Antigen (SCC)

## HEPATITIS, HIV AND SYPHILIS

HCV Ab
HIV Combo Ag/Ab
HBs Ag
HBs Ab
HBe Ag
HAV Ab
HAV IgM
Anti-HBe (HBeAb)
Dengue NS1 Antigen (NS1)
Dengue Virus IgG (Dengue IgG)
Dengue Virus IgM (Dengue IgM)
HBc Ab (Anti-HBc)
HBc IgM (Anti-HBc IgM)
HIV 1/2 Antibody (HIV 1/2 Ab)
HTLV I/II Antibody (HTLV I/II Ab)
Syphilis – Treponema pallidum Antibody (TP)

## TORCH

Cytomegalovirus IgG (CMV IgG)
Cytomegalovirus IgM (CMV IgM)
Herpes Simplex IgG I/II (HSV IgG)
Herpes Simplex IgG II (HSV-2 IgG)
Herpes Simplex IgM I/II (HSV IgM)
Rubella IgG
Rubella IgM
Toxoplasma IgG (Toxo IgG)
Toxoplasma IgM (Toxo IgM)

## GASTRIC FUNCTION

Gastrin-17 (G17)
Pepsinogen I (PGI)
Pepsinogen II (PGII)

## KIDNEY FUNCTION

Neutrophil Gelatinase-Associated Lipocalin (NGAL)

## HEPATIC FIBROSIS

Collagen Type IV (C-IV)
Hyaluronic Acid (HA)
Laminin (LN)
Procollagen III N-Terminal Peptide (PIIINP / PC-III)

## INTERSTITIAL LUNG DISEASE

KL-6 (Sialylated Carbohydrate Antigen)

## ALLERGY

Total IgE

*Not all products are available in all countries. Please contact your local SHD representative for availability in your market.*

# Assay menu — autoimmunity

Autoantibody profiles across rheumatology, neurology, hepatology and dermatology

### ANTINUCLEAR ANTIBODY (ANA) PROFILE

ANA Screen
Anti-CENP-B (Centromere B) IgG
Anti-Histone IgG
Anti-Jo-1 IgG
Anti-Mitochondrial M2 (AMA-M2) IgG
Anti-Nucleosome (Anti-Nuc) IgG
Anti-P0 (Ribosomal P Protein) IgG
Anti-PCNA IgG
Anti-PM-Scl IgG
Anti-Ro52 IgG
Anti-SS-A/Ro IgG
Anti-SS-B/La IgG
Anti-Scl-70 IgG
Anti-Sm IgG
Anti-dsDNA IgG
Anti-nRNP/Sm (U1-RNP) IgG
Anti-ssDNA IgG
Anti-α-Fodrin IgG
ENA Screen IgG

### ANTIPHOSPHOLIPID SYNDROME

Anti-Cardiolipin (aCL) IgA
Anti-Cardiolipin (aCL) IgA/G/M
Anti-Cardiolipin (aCL) IgG
Anti-Cardiolipin (aCL) IgM
Anti-Phosphatidylserine/Prothrombin (aPS/PT) IgG
Anti-Phosphatidylserine/Prothrombin (aPS/PT) IgM
Anti-β2-GP1 Domain 1 IgG
Anti-β2-Glycoprotein 1 IgA
Anti-β2-Glycoprotein 1 IgA/G/M
Anti-β2-Glycoprotein 1 IgG
Anti-β2-Glycoprotein 1 IgM
APS IgG
APS IgM
Anti-ANXA5 (Annexin A5) IgG
Anti-TN-C IgG
Anti-TN-S IgG
Anti-Vimentin (Anti-vim) IgG

### RHEUMATOID ARTHRITIS AND RELATED

Anti-CCP IgG
Anti-MCV IgG
Anti-RA33 IgG
Matrix Metalloproteinase-3 (MMP-3)
Rheumatoid Factor (RF) IgA
Rheumatoid Factor (RF) IgA/G/M
Rheumatoid Factor (RF) IgG
Rheumatoid Factor (RF) IgM

### MYOSITIS ANTIBODY PROFILE

Anti-EJ IgG
Anti-Ku IgG
Anti-MDA5 IgG
Anti-Mi-2α IgG
Anti-Mi-2β IgG
Anti-NXP2 IgG
Anti-OJ IgG
Anti-PL-12 IgG
Anti-PL-7 IgG
Anti-PM-Scl 100 IgG
Anti-PM-Scl 75 IgG
Anti-SAE1 IgG
Anti-SRP IgG
Anti-TIF1γ IgG

### ANCA AND VASCULITIS

Anti-Endothelial Cell IgA
Anti-GBM (Glomerular Basement Membrane) IgG
Anti-MPO (Myeloperoxidase) IgG
Anti-PR3 (Proteinase 3) IgG

### COELIAC DISEASE

Anti-Deamidated Gliadin Peptide (DGP) IgA
Anti-Deamidated Gliadin Peptide (DGP) IgG
Anti-Tissue Transglutaminase (tTG) IgA
Anti-Tissue Transglutaminase (tTG) IgG

### INFLAMMATORY BOWEL DISEASE

Anti-Intestinal Goblet Cell IgA
Anti-Intestinal Goblet Cell IgG
Anti-Saccharomyces cerevisiae (ASCA) IgA
Anti-Saccharomyces cerevisiae (ASCA) IgG

### AUTOIMMUNE LIVER DISEASE

Anti-LC-1 IgG
Anti-LKM-1 IgG
Anti-SLA/LP IgG
Anti-gp210 IgG
Anti-sp100 IgG
Smooth Muscle Antibody (SMA) IgG

### BULLOUS DERMATOSIS

Anti-BMZ (Basement Membrane Zone) IgG
Anti-BP180 IgG
Anti-BP230 IgG
Anti-Collagen VII (Anti-CVII) IgG
Anti-Dsg1 (Desmoglein 1) IgG
Anti-Dsg3 (Desmoglein 3) IgG
Anti-Eid IgG
Bullous Dermatosis IgG (screen)

### CNS DEMYELINATING DISEASE

Anti-Aquaporin-4 (AQP4 / QP4) IgG
Anti-MOG / Oligodendrocyte Glycoprotein (OG) IgG
Anti-Myelin Basic Protein (BP / MBP) IgG

### AUTOIMMUNE ENCEPHALITIS

Anti-AMPA1 IgG
Anti-AMPA2 IgG
Anti-ANXA2 (Annexin A2) IgG
Anti-CASPR2 IgG
Anti-DPPX IgG
Anti-GABA-B Receptor IgG
Anti-IgLON5 IgG
Anti-LGI1 IgG
Anti-NMDAR IgG
Anti-Phosphatidylethanolamine (aPE) IgG

### PARANEOPLASTIC NEURONAL ANTIGENS

Anti-Amphiphysin IgG
Anti-CV2/CRMP5 IgG
Anti-Hu IgG
Anti-Ma2/Ta IgG
Anti-Ri IgG
Anti-Yo IgG

### MEMBRANOUS NEPHROPATHY

Anti-C1q IgG
Anti-PLA2R (Phospholipase A2 Receptor) IgG

### REPRODUCTIVE AUTOANTIBODIES

Anti-Endometrial IgG
Anti-Endometrial IgM
Anti-Ovary IgG
Anti-Ovary IgM
Anti-Spermatozoa IgG
Anti-Spermatozoa IgM
Anti-Trophoblast Cell Membrane
Anti-Zona Pellucida IgG
Anti-Zona Pellucida IgM
Anti-hCG IgG

### IMMUNE THROMBOCYTOPENIA

Anti-Platelet (Anti-Thrombocyte) IgG

### IGG4-RELATED DISEASE

IgG4

*Not all products are available in all countries. Please contact your local SHD representative for availability in your market.*

# System products

## Analyzers

| | | |
|---|---|---|
| | INNOVIQURE NEXUS Chemiluminescence Immunoassay Analyzer | |
| | INNOVIQURE SPECTRUM Chemiluminescence Immunoassay Analyzer | |

## System consumables

| | | |
|---|---|---|
| | INNOVIQURE Pre-Trigger Solution | 100 mL · 1,000 tests |
| | INNOVIQURE Trigger Solution | 100 mL · 1,000 tests |
| | INNOVIQURE Wash Buffer | 10 L · 300 tests |
| | INNOVIQURE Enhanced Cleanser | 2 × 11 mL |
| | INNOVIQURE Assay Cup | 1,000 pcs |
| | INNOVIQURE Assay Cup | 1,000 pcs |

## Quality controls

| | | |
|---|---|---|
| | INNOVIQURE Liquid Cardiac Markers Plus Control | Levels 1, 2, 3 |
| | INNOVIQURE Lyophilized Immunoassay Plus Control | Levels 1, 2, 3 |
| | INNOVIQURE Lyophilized Tumor Marker Control | Levels 1, 2, 3 |
| | INNOVIQURE Lyophilized Special Immunoassay Control | Levels 1, 2, 3 |

*Reagent kits are supplied in 100 T, 200 T and 400 T pack sizes. A 200 T carton contains two 100 T cartridges and a 400 T carton contains two 200 T cartridges.*

# Quality management and regulatory status

### Certification

| | | |
|---|---|---|
| **EN ISO 13485:2016** | MMS-389-1012 | EURO CERTIFICATION (DOOEL) |
| **EN ISO 9001:2015** | QMS-389-1012 | EURO CERTIFICATION (DOOEL) |
| **EN ISO 14001:2015** | EMS-389-1012 | EURO CERTIFICATION (DOOEL) |
| **ISO/IEC 27001:2022** | ISMS-389-1012 | EURO CERTIFICATION (DOOEL) |
| **ISO 45001:2018** | OHS-389-1012 | EURO CERTIFICATION (DOOEL) |
| **GMP** | GMP-25.11.322 | DSR Certification |

Scope of certification: design and production of in vitro diagnostic test kits, control kits, calibration kits, reagents and other consumables; manufacturing, service and installation of in vitro diagnostic analyzers. The quality management system has been under third-party certification since September 2022.

### Regulatory

**Declaration of Conformity**

DB/DoC/2026-001, issued under Directive 98/79/EC, Annex III

**EUDAMED single registration number**

TR-MF-000034179

**UK Responsible Person**

DD Crown Ltd, Ashley House, Floor 4, Suite 403, 235–239 High Road, London N22 8HF, United Kingdom

**Person responsible for regulatory compliance**

Appointed in accordance with Article 15 of Regulation (EU) 2017/746

**Country of manufacture**

Türkiye — the devices are wholly manufactured at the address below

DB/BRO/INNOVIQURE/2026-001 · Rev. 01
November 2026

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