

Confirmation Letter

To: "CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE"

Tender Ref. Number: ocds-b3wdp1-MD-1729260682108

Tender Announcement Date: 18.10.2024

Subject: Confirmation of Technical Specifications for Device NEO IRIS

Dear Members of the Tender Committee,

We, **IMMUCOR Medizinische Diagnostik GmbH**, located at

Robert-Bosch-Straße 32,

63303 Dreieich,

Germany,

as a legal manufacturer of the below listed IVD Medical Devices, hereby confirm that the device Neo Iris (0064598) offered for the tender with reference number ocds-b3wdp1-MD-1729260682108 dated 18.10.2024, fully meets all the technical specifications requested.

Below is a detailed confirmation of the specifications:

- Destination: The device is intended for conducting immunohematology examinations in the blood of the donor/patient recipient.
- Requested Parameters:
 - It is a fully automated analyser with high throughput.
 - The system is an automated analytical system with an integrated or external computer (processor, monitor, keyboard, and mouse) and can be connected to the existing LIS.
 - It supports sample types such as EDTA tubes with a volume of 6-10 ml, erythrocytes from segments, and serum/plasma.
 - The processing capacity is a minimum of 60 samples per hour.
 - User login is required to access the device's menu/work program.
 - It features real-time result viewing and archiving on an external memory device.
 - The operating principle is based on the agglutination reaction (direct and/or indirect).

- It has an LCD display with a touchscreen.
- A printer is included.
- It comes with a UPS that provides a minimum of 30 minutes of backup.
- The barcode scanner can read Cod/bar, Cod 128, Cod 39, and ISBT 128.
- It has an automatic functional status monitoring system for the integrated washer, self-balancing centrifuge, and incubator, with results viewable on the device's monitor and printable.
- The device supports bidirectional LIS communication.
- The test menu includes ABO/Rh D/Kell and other blood systems, primary/reverse/confirmatory/patient/newborn testing, D antigen variants, DAT (Direct Antiglobulin Test), and IAT (Indirect Antiglobulin Test) for screening, detecting, and identifying anti-erythrocyte antibodies, and pre-transfusion blood compatibility testing.
- The instrument display language is available in English.
- Electrical network parameters are 220 V, 50 Hz.

We trust that the above information sufficiently confirms that our offered device, Neo Iris, matches all the technical specifications required by the tender.

Should you need any further information or clarification, please do not hesitate to contact us.

On behalf of the manufacturer,

Signed by José Zamora
I approve this document
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José Zamora López
VP Commercial Operations EEMEA

Company stamp

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Signed by Dr. Holger Kost
I approve this document
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05-Dec-2024

Dr. Holger Kost
Director RA/QA
PRRC (Person Responsible for
Regulatory Compliance)