IMMUNOLAB
Research and Development Department of Salmonella Center

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DECLARATION OF CONFORMITY

Manufacturer:

Research and Development Department
Of Salmonella Center IMMUNOLAB Ltd.
24 Kładki Street, 80-822 Gdansk, Poland

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Name of the *in vitro* diagnostic medical device:

Lyophilized rabbit plasma for coagulase detection (Lyophilized rabbit plasma)
versions:
Variant 1 x 2ml, catalog number POK02, code UDI-DI 5905753743769
Variant 10x2ml, catalog number POK10, code UDI-DI 5905753743776
Variant 1 x 5ml, catalog number POK05, code UDI-DI 5905753743813

Single Registration number (SRN): PL-MF-000042563

Basic UDI-DI number 590575374OSO002KD

Risk classification: Class A defined For *in vitro* diagnostic medical device (IVDR, annex VIII)

We declare that product covered by this declaration is in conformity with the relevant Union harmonisation legislation: REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU and have been marked with the sign:

CE

Harmonised specifications and standards were used for conformity assessment in order to demonstrate the safety and effectiveness of an in vitro diagnostic medical device:

SPEC/6	Final product specification of lyophilized rabbit plasma for coagulase detection
PN-EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
PN-EN ISO 15223-1:2022-01	Medical devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirement
PN-EN ISO 20417:2021-10	Medical devices -- Information to be supplied by the manufacturer
PN-EN ISO 13485:2016-04	Medical devices – Quality management systems – Requirements for regulatory purposes

We declare the implementation, maintenance and improvement of the Quality Management System in accordance with the standard PN-EN ISO 9001:2015-10 in the scope of design and development, production and sales of the aforementioned medical device for in vitro use.

Gdańsk 16.01.2025

(place, date)

Chairman of the Board, Dorota Lieder