EU Declaration of Conformity

DOC-CE2025-IVDR051-MB-01

Manufacturer Info.	Maccura Biotechnology Co., Ltd. 16#, Baichuan Road, Hi-tech Zone, 611731 Chengdu, PEOPLE'SREPUBLIC OF CHINA
Manufacturer SRN	CN-MF-000014618
European Representative Info.	CMC Medical Devices & Drugs S.L. C/Horacio Lengo Nº 18, C.P 29006, Málaga-Spain
EC-REP SRN	ES-AR-000000293
Notified Body	BSI Group The Netherlands B.V
Notified Body ID No.	2797
Basic UDI-DI	69506174IM441119DM
EMDN Code	W0105040103
Product Name	Rubella IgM Antibody Chemiluminescent Immunoassay Kit
Variants	IM4410119: 50 Tests (Control Included) IM4411119: 100 Tests (Control Included) IM4414119: 2×50 Tests (Control Included) IM4415119: 2×100 Tests (Control Included)
Certificate No.	IVDR 782850
Valid From	2025-03-19
Valid Until	2029-03-27
Conformity Assessment Procedure	Annex IX Chapter I and III of Regulation (EU) 2017/746
Classification	Class C , Rule 3d (Annex VIII)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Regulation (EU) 2017/746 on in vitro diagnostic medical devices.
All supporting documentation is retained at the premise of the manufacturer.

Applicable Regulation	REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices
CS	Not applicable
Standards	EN ISO 13485: 2016 EN ISO 14971: 2019 EN ISO 23640: 2015 EN ISO 18113-1:2024 EN ISO 18113-2:2024 EN ISO 15223-1:2021 EN13641: 2002 EN13612: 2002
Start of CE-MARK	2025-03-19
Place,Date of issue	Chengdu, 2025-03-19

Signature

Zhang Xun
Function: Person Responsibility for Regulatory Compliance

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Annex

Intended Purpose

For in vitro quantitative determination of IgG antibody to Rubella virus in human serum or plasma by immunoassay processed on Automatic Chemiluminescence Analyzer.
It is mainly used as an aid in the assessment of a patient's serological status of Rubella virus infection in individuals including women of childbearing age. This assay may be utilized with Rubella IgM result to determine recent serological response to Rubella virus.
The test results of this kit should not be used as the unique basis for pregnancy termination.
For professional use in laboratory only.

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