EU Declaration of Conformity

DOC-CE2025-IVDR050-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
Product Name	Rubella IgG Antibody Chemiluminescent Immunoassay Kit
Variants	IM4410118: 50 Tests (Control Included) IM4411118: 100 Tests (Control Included) IM4414118: 2×50 Tests (Control Included) IM4415118: 2×100 Tests (Control Included)
Certificate No.	IVDR 782850
Conformity Assessment Procedure	Annex IX Chapter I and III of Regulation (EU) 2017/746
Classification	Class C, Rule 3d (Annex VIII)

Basic UDI-DI 69506174IM441118DK

EMDN Code W0105040102

Valid From 2025-03-19

Valid Until 2029-03-27

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 18113-1:2011	EN13641: 2002
EN ISO 14971: 2019	EN ISO 18113-2:2011	EN13612: 2002
EN ISO 23640: 2015	EN ISO 15223-1:2021	

Start of CE-MARK 2025-03-19

Place,Date of issue Chengdu, 2025-03-19

Signature

Zhang Xun

Function: Person Responsibility for Regulatory Compliance

CE 2797

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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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