

EU Declaration of Conformity

DOC-CE2025-IVDR052-MB-01

Manufacturer Info.

Maccura Biotechnology Co., Ltd.
16# Baichuan Road, Hi-tech Zone, 611731 Chengdu, PEOPLE'S REPUBLIC OF CHINA

Manufacturer SRN

CN MF 000014818

European Representative Info.

CMC Medical Devices & Drugs S.L.
C/Horacio Lengo N° 18, C.P. 29006, Málaga-Spain

EC-REP SRN

ES-AR-000000793

Notified Body

BSI Group The Netherlands B.V

Basic UDI-DI 69506174IM441121D8

Notified Body ID No.

2797

EMDN Code W0105040204

Product Name

CMV IgM Antibody Chemiluminescent Immunoassay Kit

Variants

IM4410121: 50 Tests (Control Included)
IM4411121: 100 Tests (Control Included)
IM4414121: 2x50 Tests (Control Included)
IM4415121: 2x100 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 18113-1:2024 EN ISO 13641: 2002
EN ISO 14971: 2019 EN ISO 18113-2:2024 EN ISO 13612: 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



maccura

Annex

Intended Purpose

For in vitro qualitative determination of IgM antibody to cytomegalovirus 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 CMV infection in individuals including women of childbearing age. This assay may be utilized with a CMV IgG result to determine recent serological response to cytomegalovirus. The test results of this kit should not be used as the unique basis for pregnancy termination. For professional use in laboratory only.