# EU Declaration of Conformity

DOC-CE2025-IVDR053-MB-01

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| **Manufacturer Info.** | Maccura Biotechnology Co., Ltd.<br>188, 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.<br>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** | 69506174IM441120D6 |
| **EMDN Code** | W0105040203 |
| **Product Name** | CMV IgG Antibody Chemiluminescent Immunoassay Kit |
| **Variants** | IM4410120: 50 Tests (Control Included<br>IM4411120: 100 Tests (Control Included)<br>IM4414120: 2×50 Tests (Control Included)<br>IM4415120: 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.*

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| **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<br>*Function: Person Responsibility for Regulatory Compliance* |

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# Annex

**Intended Purpose**

For in vitro quantitative determination of IgG antibody to CMV 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 CMV IgM result to determine recent serological response to CMV.
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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