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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

# EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II (Class D Devices)

## No. V70 090019 0006 Rev. 00

**Manufacturer:**

**MP Biomedicals Germany GmbH**
Thüringer Straße 15
37269 Eschwege
GERMANY

SRN Manufacturer - DE-MF-000020991

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, of this regulation with a positive result. In order to maintain this certificate, the manufacturer shall submit Periodic Safety Update Reports at least annually to the notified body TÜV SÜD Product Service GmbH. Verification of manufactured class D devices according to Annex IX Sections 4.12 and 4.13 is applicable. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V70 090019 0006 Rev. 00

**Report No.:** 713296156

**Valid from:** 2024-07-15
**Valid until:** 2029-07-14

Marta Carnielli
Head of Certification IVD

**Issue date:** 2024-07-15


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| | |
|---|---|
| **Classification:** | Class D |
| **Device Group:** | W0105040619 - CORONAVIRUS |
| **Basic UDI-DI:** | 42601633107AG60SELFVR |
| **Intended Purpose:** | LAY TEST FOR ANTERIOR NASAL SWAB SPECIMEN (FOR SELF-TESTING)<br>Rapid SARS-CoV-2 Antigen Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative, non-automated determination of SARS-CoV-2 virus antigen in anterior nasal swabs from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19.<br>Rapid SARS-CoV-2 Antigen Test Card detects the SARS-CoV-2 nucleocapsid protein (N protein).<br>Rapid SARS-CoV-2 Antigen Test Card shall not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.<br>Children under 14 years of age should be assisted by an adult. |
| **Device(s):** | Rapid SARS-CoV-2 Antigen Test Card<br>Ref. No.: 07AG6001BS<br>Ref. No.: 07AG6005BS<br>Ref. No.: 07AG6007BS<br>Ref. No.: 07AG6008BS<br>Ref. No.: 07AG6020BS<br>Ref. No.: 07AG6001BSNL<br>Ref. No.: 07AG6005BSNL |


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**The validity of this certificate depends on conditions and/or is limited to the following:** -none-

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-07-15 | 713296156 | Initial issuance |


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