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**Statement of application for conformity assessment for self-tests to European Notified Body**

To whom it may concern:

This statement relates to the following product by MP Biomedicals Germany GmbH:

Product Name: Rapid SARS-CoV-2 Antigen Test Card

MP Biomedicals has submitted the application to allow for self-test status of this antigen rapid test to the German notified body as follows:

- TÜV SÜD GmbH has accepted the application of MP Biomedicals GmbH, Eschwege for the evaluation of a SARS-COV2 antigen test for lay use according to IVDD Annex III.6 or Annex IV.  
*(Die TÜV SÜD GmbH hat den Antrag der Firma MP Biomedicals GmbH, Eschwege zur Bewertung eines SARS-COV2 Antigen Tests für die Laienanwendung nach IVDD Annex III.6 oder Annex IV akzeptiert.)*
- Application for special approval according to § 11 paragraph 1 MPG for the medical device "Rapid SARS-CoV-2 Antigen Test Card" (manufacturer: MP Biomedicals Germany GmbH).  
*(Antrag auf Sonderzulassung gemäß § 11 Absatz 1 MPG für das Medizinprodukt "Rapid SARS-CoV-2 Antigen Test Card" (Hersteller: MP Biomedicals Germany GmbH).)*

**Transaction Number/ Vorgangsnummer 5640-S-076/21**

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MP Biomedicals Germany GmbH

MP Biomedicals Germany GmbH  
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