



Abbott Rapid Diagnostics Jena GmbH  
Orlaweg 1  
07743 Jena  
Germany

## Statement of Manufacturer

### Abbott Rapid Diagnostics Jena GmbH

To Whom It May Concern

August 20, 2020

We, **Abbott Rapid Diagnostics Jena GmbH**, are the legal manufacturer and regulatory owner of Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal) with reference number 41FK10 and are responsible for placing the product on the market.

Manufacturing of the Panbio™ COVID-19 Ag Rapid Test Device is conducted by the following Abbott Rapid Diagnostics Jena GmbH qualified contract manufacturer: Abbott Diagnostics Korea Inc. ("ADK"), a company located at 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea.

The contract manufacturer is responsible for the assembly and release testing of the Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal).

ADK conducts all manufacturing in a DIN EN ISO 13485: 2016 certified facility. All manufacturing and testing are conducted in compliance with Quality System Requirements in DIN EN ISO 13485: 2016.

Yours sincerely,

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(Signature)

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