532233

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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Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1 D-07743 Jena, Germany
Tel. +49(0)3641-31110 Fax +49(0)3641-3111120

(Signature)

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(10)(2e)

Abbott Rapid Diagnostics Jena GmbH

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
D-07743 Jena / Germany
Phone: +49 (0) 3641 3111-0
Fax.: +49 (0) 3641 3111-120
E-Mail: atj.info@abbott.com
Web: www.abbott.com/ooct

Managing Directors/ Geschäftsführer:
Dr. Hans Olaf Such
John Kilcoyne
John Arthur McCoy Jr.
Benjamin Edward Oosterbaan
Damian Patrick Halloran
Company reg.: HRB 207136 AG Jena
VAT No.: DE194889265

Commerzbank AG, Jena
Bank code: 82040000, Acc.: 258882000
IBAN: DE08 8204 0000 (10)(2e) (10)(2e) 01C
SWIFT (BIC): COBADEFF821
Sparkasse Jena
Bank code: 83053030, Acc.: 142093
IBAN: DE83 8305 3030 0000 1420 93
SWIFT (BIC): HELADEF1JEN