

Abbott Diagnostics Scarborough, Inc. 10 Southgate Road Scarborough, Maine 04074 USA

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## **DECLARATION OF CONFORMITY**

**DoC** #: 82 - 2021 - 02

**Legal Manufacturer:** 

**Legal Manufacturer's Address:** 

Abbott Diagnostics Scarborough, Inc.

10 Southgate Road

Scarborough, Maine 04074 U.S.A.

With a second site at:

14 Washington Avenue

Scarborough, Maine 04074 U.S.A.

**EC Representative's Name:** 

EC Representative's Address:

**EMERGO Europe** 

Prinsessegracht 20 2514 AP, The Hague The Netherlands

declares, that the product

**Product Name and Model(s):** 

ID NOW™ COVID-19 (191-000)

ID NOW™ COVID-19 Control Swab Kit

(190-080)

COVID-19 Swab Transport Tube Accessory Pack

(190-010)

as described above conforms with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

## Additional information:

Management System:

A-028, Quality Manual

Conformity Pathway:

Annex III

Classification:

Self - declaration

Scarborough, Maine, USA

01 October 2020

Emily Deane

Sr. Director of Quality Assurance and Regulatory Compliance