



Abbott Diagnostics Scarborough, Inc.
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Scarborough, Maine 04074
USA

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DECLARATION OF CONFORMITY

DoC #: 08 - 2024 - 11

Legal Manufacturer: **Abbott Diagnostics Scarborough, Inc.**
Legal Manufacturer's Address: 10 Southgate Road
Scarborough, ME 04074 U.S.A.

With additional sites at:
14 Washington Avenue
Scarborough, Maine 04074 U.S.A.

6 Lincoln Avenue
Scarborough, Maine 04074 U.S.A.

5 Bradley Drive
Westbrook, Maine 04092 U.S.A.

EC Representative's Name: **EMERGO Europe**
EC Representative's Address: Prinsessegracht 20
2514 AP, The Hague
The Netherlands

declares, that the product
Product Name and Model(s): BinaxNOW™ Malaria (660-000)
BinaxNOW™ Malaria (66005)
BinaxNOW™ Malaria Positive Control Kit (665-010)

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



Abbott

Scarborough, Maine, USA
20 December 2021

A handwritten signature in blue ink, appearing to read 'Betsy Graves', is positioned above a horizontal line.

Betsy Graves
Director of Quality Assurance