



Alere Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074 USA
207.730.5750
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ORIGINAL

DECLARATION OF CONFORMITY

DoC #: 90 - 2015 - 04

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

EC Representative's Name: EMERGO Europe
EC Representative's Address: Molenstraat 15
2513 BH, The Hague
The Netherlands

declares, that the product
Product Name and Model(s): Alere™ BinaxNOW® Nasopharyngeal Swab Pack (400-065)

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
21st January, 2013


Emily Deane, Sr. Manager QA/RC



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Marie Gole
19 June 2017