



Alere Scarborough, Inc.  
10 Southgate Road  
Scarborough, ME 04074 USA  
207.730.5750  
207.730.5717

ORIGINAL

DECLARATION OF CONFORMITY

DoC #: 04 - 2015 - 06

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® RSV Card (430-000)  
Alere™ BinaxNOW® RSV Card (430-022)

Alere™ BinaxNOW® RSV Control Swab Kit (430-080)

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  
21<sup>st</sup> January, 2013

  
Emily Deane, Sr. Manager QA/RC



Alere International Ltd.  
Parkmore East Business Park  
Morris Code Ballybrit  
19 June 2017 Galway  
Ireland  
Reg No. 495964