



10 Southgate Road  
Scarborough, Maine 04074 USA  
phone 207.730.5750  
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# ORIGINAL

## DECLARATION OF CONFORMITY

DoC #: 07 - 2018 - 09

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

With a second site at:  
14 Washington Avenue  
Scarborough, ME 04074 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): Alere™ BinaxNOW® *Streptococcus pneumoniae* Antigen Card (710-000)  
Alere™ BinaxNOW® *Streptococcus pneumoniae* Antigen Card (710-012)  
Alere™ BinaxNOW® *Streptococcus pneumoniae* Antigen Card (710-100)  
Alere™ BinaxNOW® *Streptococcus pneumoniae* Control Swab Pack  
(710-010)

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  
20 April 2017

  
Emily Deane  
Director of Quality Assurance and Regulatory Compliance



Alere International Ltd.  
Parkmore East Business Park  
Ballybrit  
Galway  
Ireland  
Reg No. 495964  
*Marie Gade*  
*19 June 2017*