



10 Southgate Road
Scarborough, Maine 04074 USA
phone 207.730.5750
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ORIGINAL

DECLARATION OF CONFORMITY

DoC #: 09 – 2018 - 10

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(s)
Product Name and Model(s): Alere™ BinaxNOW® *Legionella* Urinary Antigen Card (852-000)
Alere™ BinaxNOW® *Legionella* Urinary Antigen Card (852-012)
Alere™ BinaxNOW® *Legionella* Urinary Antigen Card (852-100)
Alere™ BinaxNOW® *Legionella* Control Swab Pack (852-010)

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
Monie Gade
19 June 2017