

DECLARATION OF CONFORMITY

DoC #: 20 - 2015 - 06

Legal Manufacturer:

Legal Manufacturer's Address:

Alere Scarborough, Inc.

10 Southgate Road

Scarborough, ME 04074 U.S.A.

EC Representative's Name: EC Representative's Address:

EMERGO Europe Molenstraat 15

2513 BH, The Hague The Netherlands

declares, that the product

Product Name and Model(s):

Alere NMP22[®] Test (D1100E) Alere NMP22[®] Urine Collection Kit (D2100E)

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