Declaration of Conformity

as per Annex III of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998

Document No.: **DOC-2017-50**

Manufacturer:
Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876
USA

Authorized Representative:
Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim
Germany

Roche Molecular Systems declares that the in vitro diagnostic medical device:

Product Name: **cobas®** 4800 System generic reagents

P/N:
05235804190: cobas® 4800 System Sample Preparation Kit, 960 Tests
05235782190: cobas® 4800 System Sample Preparation Kit, 240 Tests
05235847190: cobas® 4800 System Control Diluent Kit
05235871190: cobas® 4800 System Wash Buffer Kit, 960 Tests
05235863190: cobas® 4800 System Wash Buffer Kit, 240 Tests
05235839190: cobas® 4800 System Liquid Cytology Preparation Kit, 960 Tests
05235812190: cobas® 4800 System Liquid Cytology Preparation Kit, 240 Tests
06768318190: cobas® 4800 System Internal Control Kit 1, 20 Runs
06768253190: cobas® 4800 System Lysis Kit 1, 240 Tests
06768270190: cobas® 4800 System Lysis Kit 1, 960 Tests

Complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The Manufacturer agrees to develop, implement, and maintain a documented post-production monitoring process, including the notification of reportable events, under the European Medical Device Vigilance System Guidelines.

Branchburg, NJ

20 March 2017

Nicholas M. Solimo
Vice President, RMD Quality Management