

## DECLARATION

The undersigned, Mrs. Joke Doutreloigne, Consultant at Qarad b.v.b.a.,

hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products:

| IVD name                                       | Catalogue nr.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| One Step Cotinine (COT)<br>Urine Test          | W139-S / W139-C / W139-P                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| One Step Ethyl Glucuronide<br>(EtG) Urine Test | W140-S / W140-C / W140-P                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Multidrug tests                                | <p>Panel, W2002-P, W2003-P, W2004-P, W2005-P, W2006-P, W2007-P, W2008-P, W2009-P, W2010-P, W2011-P, W2012-P, W2013-P, W2014-P, W2015-P, W2016-P</p> <p>Cup, W2002-CU, W2003-CU, W2004-CU, W2005-CU, W2006-CU, W2007-CU, W2008-CU, W2009-CU, W2010-CU, W2011-CU, to W2012-CU</p> <p>T-Cup, W502-CU2, W503-CU2, W504-CU2, W505-CU2, W506-CU2, W507-CU2, W508-CU2, W509-CU2, W510-CU2, W511-CU2, W512-CU2, W513-CU2, W514-CU2, W515-CU2, W516-CU2, W517-CU2, to W518-CU2</p> <p>Q-Cup, W502-CU3, W503-CU3, W504-CU3, W505-CU3, W506-CU3, W507-CU3, W508-CU3, W509-CU3, W510-CU3, W511-CU3, W512-CU3, W513-CU3, W514-CU3, W515-CU3, W516-CU3, W517-CU3, to W518-CU3</p> |

The notification to the Belgian Competent Authorities has been carried out on November 19<sup>th</sup>, 2015 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.



Joke Doutreloigne.

Qarad b.v.b.a.  
Authorized Representative