

DECLARATION

The undersigned, Mrs. Agnes Goris, 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 excluding 6 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:

name IVD	Catalogue nr.
Wondfo® Blood Gas Analyzer	BGA-101
Wondfo® Blood Gas Analyzer Test Card	W459-C7P4-M, W460-C7P4-M W461-C7P4-M, W462-C7P4-M W463-C7P4-M, W464-C7P4-M W465-C7P4-M, W466-C7P4-M W459-C7P4-E, W460-C7P4-E W461-C7P4-E, W462-C7P4-E W463-C7P4-E, W464-C7P4-E W465-C7P4-E, W466-C7P4-E
Wondfo® Blood Gas Analyzer Control	W847-L, W847-M, W847-H, W848, W849-L, W849-H
Wondfo® Blood Gas Analyzer Reagent Pack	W451-Z0P4-G, W451-Z0P4-I

The notification to the Belgian Competent Authorities has been carried out on April 30, 2018 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.



Agnes Goris

Qarad b.v.b.a.
Authorized Representative