qarad
European Regulatory Services

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.
Finecare™ Carcino-embryonic Antigen Control	W820-L, W820-M, W820-H
Diagnostic Kit for IgM Antibody to Human Enterovirus71 (Immunochromatographic Assay)	W141-C, W141-S
Finecare™ Carcino-embryonic Antigen Quantitative Rapid Test (Lateral Flow Immunoassay)	W226
Finecare™ cTnI and NT-proBNP Quantitative Rapid Test (Lateral Flow Immunoassay)	W223
Finecare™ cTnI/NT-proBNP Multi-Control	W821-L, W821-M, W821-H

The notification to the Belgian Competent Authorities has been carried out on March 25th, 2016 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

Digitally signed by Varman Irina
Date: 2021.06.24 11:36:29 EEST
Reason: MoldSign Signature
Location: Moldova