



European Regulatory Services

## DECLARATION

The undersigned, Mrs. Eline Heylen, 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™ BNP (B-type natriuretic) Rapid Quantitative Test                          | W222          |
| Finecare™ SAA (Serum Amyloid A Protein) Rapid Quantitative Test                     | W221          |
| Finecare™ T4 (Thyroxine) Rapid Quantitative Test                                    | W232          |
| Finecare™ TSH (Thyroid - stimulating hormone) Rapid Quantitative Test               | W220          |
| Finecare™ β 2-MG (Beta-2-microglobulin) Rapid Quantitative Test                     | W229          |
| Finecare™ NGAL (Neutrophil gelatinase-associated lipocalin) Rapid Quantitative Test | W228          |

The notification to the Belgian Competent Authorities has been carried out on June 17<sup>th</sup>, 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.

Eline Heylen

Qarad b.v.b.a.  
Authorized Representative