EC Declaration of Conformity

Manufacturer:

Name:

Address:

European Representative:

Name:

Address:

Product Name: 2019-nCoV IgG / IgM Detection Kit (Colloidal Gold-Based)

Model: Cassette / Dipstick

Classification: Other Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III

We herewith declare that the above mentioned products meet the transposition into nationallaw,the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-2:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 23640:2015, EN 13641:2002, EN 1041:2008, ISO 15223-1:2016

CE