

EC Declaration of Conformity

Manufacturer:

Name: Ningbo Beautiful Life Medical Biotechnology Development Co., Ltd.
Address: Room 305, Building 4, NO.7 Chuangye Avenue, Free Trade West Zone,
Ningbo, China

European Representative:

Name : Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

Product Name: Saliva SARS-Cov-2 (2019-nCoV) Antigen Combined Test Kit
(Nanocarbon Assay)

Cat: NBMLRS-XG-S1

Model: Cassette

Classification: Other Device of IVDD 98/79/EC

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

We herewith declare that the above mentioned product meets the transposition into national law, 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 ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-2:2011, EN ISO18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO23640:2015, EN 13641:2002, EN 1041:2008, ISO 15223-1:2016

Signature:

Name: Xiaoli Tian

Position: General Manager

Place: Ningbo

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