EC Declaration of Conformity

Manufacturer:
Name：
Address：

European Representative:
Name:
Address:

Product Name: Multi-Drug Rapid Test (Oral Fluid)
Model: Cassette/Cup/Device
Classification: Other Device of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding point 6)
EDMA Code:

We, herewith declare that we are exclusively responsible for this declaration of conformity.We herewith declare that the above mentioned products meet 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

Standard Applied: EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Place, Date of Issue: in Hangzhou on 18/12/2019

Signature: 26/05/2021
Name: Date