

Declaration of Conformity

Manufacturer: Hangzhou Realy Tech Co., Ltd.
4th Floor, #12 Building, Eastern Medicine Town, Xiasha
Economic & Technology Development, 310018 Hangzhou,
Zhejiang, P. R. China
whose single Luxus Lebenswelt GmbH
Authorized EU- Kochstr.1, 47877, Willich, Germany
Representative: DIMDI: DE/0000047791
Lin Sun
Tel: 0049- 1715605732
E-mail: info.m@luxuslw.de

Product Name: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test
Cassette (swab)

Classification: **Others of ANNEX II of IVDD**

Conformity Assessment Route: **Annex III**

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.

General applicable directives:

In Vitro Diagnostic Medical Devices DIRECTIVE 98/79/EC

Harmonized standards:

EN ISO 13485: 2016;
EN ISO 15223-1:2016;
EN ISO 14971: 2012;
EN ISO 13612:2002;
EN ISO 17511:2003;
EN ISO 18113-1:2011;
EN ISO 18113-2:2011;
EN ISO 23640:2015.

Signature: 
Name:
Title: general manager
Position: Hangzhou



2020.8.12