



# Certificate of Conformity

**Manufacturer:** Beijing Jinwofu Bioengineering Technology Co., Ltd.

**Address:** Room 206, 1st Building, No. 26, Jinyuan Road, Daxing District, Beijing, China

**EU Authorised Representative:**

Osmunda Medical Technology Service GmbH

Address: Treskowallee 108, 10318 Berlin, Germany

DIMDI code: DE/0000047267

**Registration number:** DE/CA76/IVD0015/007

**Device:** Novel Coronavirus (SARS-COV-2) Antigen Rapid Test (Product Code: C3042) **Classification (IVDD, Annex II):** IVD Device other than the ones listed in Annex II-IVDD 98/79 as List A, List B and Self testing

**Conformity assessment route:** ANNEX III

We herewith declare that the above-mentioned product meets the provisions of the following EC Council Directives and Standards (IVDD 98/79/EC). All supporting documentation is retained under the premises of the manufacturer.



**General applicable directive:**

In Vitro Diagnostic Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 (IVDD 98/79/EC).

**Standard Applied:**

EN ISO 13485:2016	EN ISO 14971:2012	EN 13641:2002	EN ISO 18113-1:2011
EN ISO 18113-2:2011	BS EN ISO 15223-1:2016	EN 13612:2002	EN ISO 23640:2015

**Signature:**

**Legal representative**

**Date of Issue:**

6<sup>th</sup> May 2021