

EC Declaration of Conformity

Manufacturer:

Name: HANGZHOU ALLTEST BIOTECH CO., LTD

Address: # 550, Yinhai Street, Hangzhou Economic & Technological Development Area,
Hangzhou-310018, P.R. China

European Representative:

Name: CMC Medical Devices & Drugs S.L.

Address: C/ Horacio Lengo 18, CP29006, Málaga-Spain

Product Name: Bordetella pertussis Antigen Rapid Test

Cat. No.: IBP-502

Model: Cassette

Classification: Other Device, non-listed in Annex II of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III, excluding article 6

We, HANGZHOU ALLTEST BIOTECH CO., LTD., 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 ISO14971:2019, EN 13975:2003, EN ISO
18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, ISO 17511:2020, EN
ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2021

Place, Date of Issue: in Hangzhou on 15/05/2022

Signature: 

Name: GAO FEI (Position: General Manager)

Name: Gao Fei

Position: General Manager

