

EC Declaration of Conformity

Manufacturer:

Name: Assure Tech. (Hangzhou) Co., Ltd.
Address: Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou, 310011 Zhejiang, P.R. China

Whose Authorized Representative:

Name: MedUnion S.L. (ES-AR-000019366)
Address: Carrer de Tapioles, 33, 2-1,
Barcelona, 08004, Spain
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We, Assure Tech. (Hangzhou) Co., Ltd. (Manufacturer), here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them. The declaration of conformity is exclusively under the responsibility of Assure Tech. (Hangzhou) Co., Ltd. (Manufacturer).

Product Name: COVID-19 & Influenza A/B & Adenovirus & RSV Antigen Nasal Test Kit

Registration number: PS/RPS/5121/2022

Classification: Others

Conformity Assessment Route: IVDD 98/79/EC Annex III (excluding section 6).

Applicable Standards:

EN ISO 13485:2016

EN 13975:2003

EN 13612:2002/AC:2002

EN ISO 14971:2019

EN ISO 15223-1:2021

EN 13641:2002

EN ISO 18113-1:2011

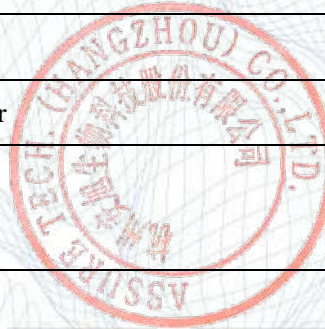
EN ISO 18113-2:2011

IEC 62366-1: 2015

EN ISO 23640:2015



Name of Authorized Signatory	Eric Ling
Position Held In The Company	General Manager
Signature	
Date	2022.05.10
Place	Hangzhou, China



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