



DECLARATION OF CONFORMITY

Linkcare Health Services S.l.
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**COVID-19 ANTIGEN TEST KIT (Colloidal Gold)
 (Nasal/Nasopharyngeal/Oropharyngeal/Sputum/Saliva)**

REF

**AGSWNPR21-01 AGSWNPR21-02
 AGSWNPR21-04 AGSWNPR21-05
 AGSWNPR21-25**

**AGSLVPR21-01 AGSLVPR21-02
 AGSLVPR21-04 AGSLVPR21-05
 AGSLVPR21-25**

Classification

Other Device of IVDD 98/79/EC

Conformity Assessment Route

IVDD 98/79/EC Annex III

EDMA Code

15 70 90 90 00

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards

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 ISO13975:2003, EN ISO 18113-1:2011,
 EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003,
 EN ISO 23640:2015, EN ISO 13641:2002, EN ISO 15223-1:2012**

After preparation of the necessary technical documentation as well as the conformity declaration the required CE marking can be affixed on the product.

Other relevant directives must be observed.



Date of issue: 26/04/2021