Zertifikat - Certificat - Certificado - Certificate - Certifika - сертификат

DECLARATION OF COMFORMITY

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LINKCARE (DIAGNOS) COVID-19 RAPID ANTIGEN TEST (Colloidal Gold)
(Nasal/Nasopharyngeal/Oropharyngeal/Sputum/Saliva)

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