NESAPOR EUROPA

CE

EC DECLARATION OF CONFORMITY

NESAPOR EUROPA, SL

Suïssa, 34 08338 Premià de Dalt (BCN)
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Product Name	COVID-19 Antigen Rapid Test Kit NASAL MEDICAL
Ref	NKDCMNS
Classification	Other Device According to directive 98/79/EC. Non annex III, non self test
Conformity Assessment Route	Annex III of Directive 98/79/EC
General applicable directives	DIRECTIVE 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices. All applicable harmonized standards.
EDMA CODE	15 70 90 90 00
Intended Use	For *in vitro* qualitative detect of SARS-CoV-2 nucleocapside antigen in nasal swab specimen directly from individuals who are suspected of COVID-19 by their healthcare provider. This test is only provided for use by clinical laboratories healthcare workers for point-of-care testing, and not for at home testing (Self Testing).

We the manufacturer, herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC COUNCIL Directives and Standards, on *In-Vitro* Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process, as well as the conformity declaration CE marking can be affixed on the product.

Premià de Dalt, 18/03/2021

Signature:
Name: Francesc Giménez
POSITION: General Manager