

# CERTIFICATE OF IVD NOTIFICATION



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Order No.: GR 0521- 2021

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**Annex A - List of Devices**

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class
1.	C8602CY	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	Coronavirus	The test is applicable to detect the antigen of Severe Acute Respiratory Syndrome Coronavirus 2(SARS-CoV-2) Antigen in human nasal swab/throat swab/saliva samples in vitro.	64787	Others

\* Annex A is part of the Agreement.

\*\* The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 &amp; Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 &amp; 3.3)

\*\* The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

**Obelis s.a.****Signature:** \_\_\_\_\_

  
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