TABEL TESTE INREGISTRATE IN 30.03.2020 LA NIVELUL UE

Nr crt	Producator	Reprezentant autorizat in UE	Date de contact	Denumire produs	Descriere produs	Statul Membru responsabil de inregistrare
1	PCL. Inc., Republic of Korea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	PCL COVID19 Ag Rapid FIA; PCL COVID19 IgG/IgM Rapid Gold	PCL COVID19 Ag Rapid FIA is an in vitro diagnostic medical device applying dual antibody sandwich reaction and fluorescence immunochromatographic assay to qualitatively detect SARS CoV 2 antigen in human oropharyngeal / nasopharyngeal specimens and sputum specimens. PCL COVID19 IgG/IgM Rapid Gold is an in vitro diagnostic medical device for qualitative detection of IgG and IgM antibodies of COVID19 infection in human serum, plasma, venous blood and capillary blood. For professional use only. Internal admin-No.: PCL-07, PCL-07-01	DE - GERMANIA
2	SCREEN ITALIA SRL, Italia	NA	info@screenitalia.it	SCREEN TEST COVID-19 - 2019-NCOV IGG/IGM RAPID TEST CASSETTE	---	IT - ITALIA
3	BIOPLASTIC SOCIETA IN ACCOMANDITA SEMPLICE DI PETRALIA MARIO, Italia	NA	VIA ALESSANDRO DUDAN 9, ROMA,00143	COVID-19 IGG/IGM RAPID TEST	---	IT – ITALIA
4	Swedicine AB, Suedia	NA	Beiar@.Swedicine.se	COVID-19	---	SE – SUEDIA
5	Roche Molecular Systems, Inc., SUA	Roche Diagnostics, GmbH, Germania	ralf.zielenski@roche.com	SARS-CoV-2 Control Kit	cobas® SARS-CoV-2 test for use on the cobas® 6800/8800 Systems is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples.	DE - GERMANIA
6	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 IgG Antibody (ELISA)	The kit Assay is an Enzyme immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human Serum or Plasma	DE - GERMANIA
7	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 IgM Antibody (ELISA)	The kit Assay is a Enzyme linked immuno Assay for qualitative detection of IgM antibody to the new coronavirus in human Serum and plasma	DE - GERMANIA

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8	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 IgG/IgM Antibody (Colloidal Gold)	Immunchromatographic technology for qualitative determination of IgG/IgM antibodies against SARS-CoV-2 in human Serum, Plasma or whole blood	DE - GERMANIA
9	Shanghai Kehua Bio-engineering Co., Ltd., China	DIAneering Diagnostics Engineering & Research, Germania	eberhard.spanuth@t-online.de	Diagnostic kit for SARS-CoV-2 Nucleic Acid Real Time PCR	The PCR test is used for the qualitative detection of SARS-CoV-2 nucleic acid by targeting OFRlab Region, N and E protein genes of the viral Genome	DE - GERMANIA
10	PCL. Inc., Republic of Korea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	PCLMD# nCoV one step RT-PCR kit	The PCLMDTM nCoV one step RT-PCR Kit is a qualitative real-time reverse transcription PCR (RT-PCR) IVD medical device for the detection of SARS-CoV-2 in human nasopharyngeal specimen. For professional use only.	DE - GERMANIA
11	BioCore Co.Ltd., Republic of Korea	Medical Technology Promedt Consulting GmbH, Germania	info@mt-procons.com	BioCore 2019-nCoV Real Time PCR Kit	This product qualitatively confirms the presence or absence of a new coronavirus (SARS CoV2, Covid-19) using reverse-transcription Real Time Polymerase Chain Reaction in sputum, oropharyngeal and nasopharyngeal specimens. Internal admin-No.: BIC-01	DE - GERMANIA
12	QIAGEN GmbH, Germania	NA	RegulatoryAffairs@qiagen.com	QIAstat-Dx Respiratory SARS-CoV-2 Panel	The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative test intended for analyzing nasopharyngeal swab (NPS) samples for the presence of viral or bacterial nucleic acids. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is able to accept both dry swabs a and transport medium liquid samples. The assay is designed for use with the QIAstat-Dx Analyzer 1.0 for integrated nucleic acid extraction and multiplex real-time RT-PCR detection.	DE - GERMANIA

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13	BGI EUROPE A/S, Danemarca	NA	Ole Maaløes Vej 3 2200 København N	Real-time fluorescent RT-PCR kit for detecting 2019-nCoV	The kit is a qualitative in vitro nucleic acid amplification assay to detect the new coronavirus identified in China in 2019 using Reverse transcription PCR in specimen of Throat swab and Bronchoalveolar Lavage Fluid (BALF)from suspects.In end of 2019, some pneumonia cases were reported in Wuhan, China and the pathogen was confirmed as a new strain. World Health organization has named the newly identified coronavirus as 2019-nCoV. Although more intensive researches must be conducted later to well understand the virus, in response to the emergency in disease control, simple and rapid kit is necessary to identify the virus timely and implement efficient interventions to contain the spread. The kit will qualitatively detect the nucleic acid of 2019-nCoV in specimen from suspects enabling to assess the infection situation of 2019-nCoV in suspects in clinical and public health practice.	DK - DANEMARCA
14	HANGZHOU ALLTEST BIOTECH CO., LTD., China	ALCOOLTEST MARKETING ITALY S.R.L., Italia	ALCOOLTEST@PEC.IT	AMIINCP-402S -2019-NCOV FIRNGERTIP	---	IT - ITALIA
15	HANGZHOU ALLTEST BIOTECH CO., LTD., China	ALCOOLTEST MARKETING ITALY S.R.L., Italia	ALCOOLTEST@PEC.IT	2019-NCOV CORONAVIRUS AMI-INCP402	---	IT – ITALIA
16	INTERMEDICAL S.R.L., Italia	NA	INTERMEDICALSRL@CGN.LEGALMAIL.IT	2019-NCOV IGG/IGM	---	IT – ITALIA
17	Hangzhou Laihe Biotech Co., Ltd., China	Riomavix S.L., Spania	Calle de Almansa 55, 1D, 28039 Madrid	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	The LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) is intended for the qualitative detection of IgM/IgG antibodies against novel coronavirus in human serum, plasma or whole blood from patients with clinical suspicion of Novel coronavirus (2019-nCoV) infection. For in vitro diagnostic use	ES - SPANIA