

CERTIFICATE OF IVD NOTIFICATION



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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/EDMS Code	Class
1.	S1012E	Sample release reagent	Reagents for DNA and/or RNA extraction and preparation; bacteria and/or virus	The Sample release reagent is intended for use to release the nucleic acid from the specimens including cloned bacteria liquid, serum, plasma, urine and cotton swab elution, which are processed by concentrate and then centrifuged immediately. The released nucleic acid can be directly used for regular molecular biology tests. Components of the Diagnostic Kit: Concentrate Nucleic acid lysis buffer	15.90.40.01	Others
2.	S1013E	Sample Release Reagent	Reagents for DNA and/or RNA extraction and preparation; bacteria and/or virus	The Sample Release Reagent is intended for use to release the nucleic acid from the specimens including cloned bacteria liquid, serum, plasma, urine and cotton swab elution, which are processed by concentrate and then centrifuged immediately. The released nucleic acid can be directly used for regular molecular biology tests. Components of the Diagnostic Kit: Sample Release Reagent	15.90.40.01	Others
3.	S3045E	α -Thalassemia Gene Diagnostic Kit (gap-PCR)	Thalassaemia	The α -Thalassemia Gene Diagnostic Kit (gap-PCR) is intended to be used for detection of the presence of α -thalassaemia gene in peripheral blood sample. The diagnostic kit can detect four types of deficiency α -thalassaemia genes (α -SEA, α -3.7, α -4.2, α -THAI). For in vitro diagnostic use only. For professional use only. Components of the Diagnostic Kit: α -Thalassemia-PCR Mix α -Thalassemia-Enzyme Mix α -Thalassemia-Positive Control α -Thalassemia-Negative Control	16.01.01.11	Others
4.	S3065E	<i>Mycoplasma genitalium</i> DNA Diagnostic Kit (PCR-Fluorescence Probing)	Mycoplasma Detection by NA Reagents	<i>Mycoplasma genitalium</i> DNA Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of <i>Mycoplasma genitalium</i> (MG)-DNA in samples of genital tract secretion. The detection result can be used as an aid in the diagnosis of a MG infection. The test provides a molecular diagnostics-based solution for diagnosis of <i>Mycoplasma genitalium</i> infected disease. For in vitro diagnostic use only. For professional use only. Components of the Diagnostic Kit: MG-Enzyme Mix MG-PCR Mix MG-Internal Control MG-Negative Control MG-Positive Control	15.01.08.40	Others
5.	S3072E	<i>Legionella pneumophila</i> DNA Diagnostic Kit (PCR-Fluorescence Probing)	Legionella Detection by NA Reagents	The <i>Legionella pneumophila</i> DNA Diagnostic Kit (PCR-Fluorescence Probing) is based on real-time fluorescence quantitative PCR method and used for qualification detection of <i>Legionella pneumophila</i> DNA from human nasopharyngeal swab specimen. The detection result can be used as an aid in the diagnosis of <i>Legionella pneumophila</i> infection. For in vitro diagnostic use only. For professional use only. Components of the Diagnostic Kit: Concentrate LP-Lysis Buffer LP-PCR Mix LP-Internal Control LP-Enzyme Mix LP-Negative Control LP-Positive Control	15.01.05.40	Others

6.	S3074E	<i>Coxsackievirus A6</i> Real Time RT-PCR Diagnostic Kit (PCR-Fluorescence Probing)	Enterovirus - NA Reagents	<p>The <i>Coxsackievirus A6</i> Real Time RT-PCR Diagnostic Kit (PCR-Fluorescence Probing) is an in vitro nucleic acid amplification test for the qualitative detection of Coxsackievirus A6 nucleic acids in clinical throat swab by applying real-time fluorescence quantitative PCR technology. It is intended for use as an aid in the differential diagnosis of patients with suspected pathogens infection.</p> <p>For in vitro diagnostic use only. For professional use only.</p> <p>Components of the Diagnostic Kit:</p> <p>RNA Extraction Solution 1 RNA Extraction Solution 2 RNA Extraction Solution 3 RNA Extraction Solution 4 RNA Elution Buffer CA6 Internal Control CA6 PCR Mix CA6 Enzyme Mix CA6 Positive Control CA6 Negative Control</p>	15.04.40.02	Others
7.	S3102E	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	Coronavirus - NA Reagents	<p>Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) is used for qualitative detection of the ORF1ab and N genes of novel coronavirus (2019-nCoV) in nasopharyngeal swab, oropharyngeal swab, alveolar lavage fluid, sputum, serum, whole blood and feces from suspected pneumonia cases with novel coronavirus infection, patients with suspected clusters of novel coronavirus infection, and other patients requiring diagnosis or differential diagnosis of novel coronavirus infection.</p> <p>For in vitro diagnostic use only. For professional use only.</p> <p>Components of the Diagnostic Kit:</p> <p>2019-nCoV-PCR Mix 2019-nCoV-PCR-Enzyme Mix 2019-nCoV-PCR-Positive Control 2019-nCoV-PCR-Negative Control</p>	15.04.40.19	Others
8.	S1014E	Sample Release Reagent	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	<p>The Sample Release Reagent is intended for the pretreatment of the samples to be tested, the substances to be tested in the specimens can be released from the state of combining with other substances to facilitate the use of in vitro diagnostic reagents or instruments to test substances to be tested. Such as folate release agent, vitamin B12 release agent.</p> <p>Components of the Diagnostic Kit:</p> <p>Sample Release Reagent</p>	15.90.40.01	Others
9.	S1015E	Sample Release Reagent	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	<p>The Sample Release Reagent is intended for the pretreatment of the samples to be tested, the substances to be tested in the specimens can be released from the state of combining with other substances to facilitate the use of in vitro diagnostic reagents or instruments to test substances to be tested. Such as folate release agent, vitamin B12 release agent.</p> <p>Components of the Diagnostic Kit:</p> <p>Sample Release Reagent 1 Sample Release Reagent 2 Sample Release Reagent 3 Sample Release Reagent 4 Sample Release Reagent 5</p>	15.90.40.01	Others
10.	X1002E	Sample Storage Reagent	Reagents for DNA and/or RNA extraction and preparation: bacteria and/or virus	<p>The sample release reagent is intended for preservation and transportation of cells from human body.</p> <p>For in vitro analysis and testing use only, not for therapeutic use.</p> <p>Components of the Diagnostic Kit:</p> <p>Sample Storage Reagent</p>	15.90.40.01	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 (IVD 98/79/EC).

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