

CERTIFICATE

EC Declaration of Conformity

Manufacturer:
CITEST DIAGNOSTICS INC.
170-422 Richards Street, Vancouver BC V6B 2Z4 Canada
Single Registration Number: CA-MF-000022516

European Representative:
VIDAQUICK BIOTECH S.L.
No.132, Rosello Street, Barcelona, Barcelona Province, 08036, Spain
Single Registration Number: ES-AR-000048138

Herewith declare that the products described below:

Product name: Refer to Attachment I
Cat No: Refer to Attachment I
Classification: Self-declaration of IVDD 98/79/EC
Conformity Assessment Route: IVDD 98/79/EC Annex III (including section 6)

meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

General applicable 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 ISO 13485:2016, EN ISO 14971:2019, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, ISO 20916:2019, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2021, EN 62366-1:2015

Place, Date: Vancouver, June 26, 2025

Signature:



Name:

Fu Yanping

Title:

General Manager

CITEST DIAGNOSTICS INC



Attachment I Product List

Cat.no.	Product Name	Certificate No.	Classification under IVDD
Fluorescence Immunoassay			
FI-VB12-CT302	Vitamin B12 Test Cassette	RPS/568/2025	Self-declaration Others
FI-SBNBP-CT402	High-Sensitivity NT-proBNP Test Cassette	RPS/568/2025	Self-declaration Others
FI-SCTT-CT402	High-Sensitivity Cardiac Troponin T Test Cassette	RPS/568/2025	Self-declaration Others
FI-AFP-302	AFP Test Cassette	RPS/1138/2025	Self-declaration Others
FI-CTI-402	Cardiac Troponin I Test Cassette	RPS/1138/2025	Self-declaration Others
FI-CKMB-402	CK-MB Test Cassette	RPS/1138/2025	Self-declaration Others
FI-CRP-402	CRP Test Cassette	RPS/1138/2025	Self-declaration Others
FI-CYSC-402	Cys-C Test Cassette	RPS/1138/2025	Self-declaration Others
FI-DDM-402	D-Dimer Test Cassette	RPS/1138/2025	Self-declaration Others
FI-FSH-402	FSH Test Cassette	RPS/1138/2025	Self-declaration Others
FI-HBA-402	HbA1c Test Cassette	RPS/1138/2025	Self-declaration Others
FI-HFA-402	H-FABP Test Cassette	RPS/1138/2025	Self-declaration Others
FI-LH-402	LH Test Cassette	RPS/1138/2025	Self-declaration Others
FI-ALB-102	Microalbumin Test Cassette	RPS/1138/2025	Self-declaration Others
FI-MYO-402	Myoglobin Test Cassette	RPS/1138/2025	Self-declaration Others
FI-NAGL-102	NGAL Test Cassette	RPS/1138/2025	Self-declaration Others
FI-NBNP-402	NT-pro BNP Test Cassette	RPS/1138/2025	Self-declaration Others
FI-PCT-402	PCT Test Cassette	RPS/1138/2025	Self-declaration Others
FI-STA-502	Srep A Test Cassette	RPS/1138/2025	Self-declaration Others
FI-T4-302	T4 Test Cassette	RPS/1138/2025	Self-declaration Others
FI-TSH-302	TSH Test Cassette	RPS/1138/2025	Self-declaration Others
FI-BMG-402	Beta2MG Test Cassette	RPS/1138/2025	Self-declaration Others
FI-NCP-CT402	COVID-19 IgG/IgM Test Cassette	RPS/1138/2025	Self-declaration Others
FI-NCP-CT502	COVID-19 Antigen Test Cassette	RPS/1138/2025	Self-declaration Others
FI-CSG-CT402	COVID-19 S-RBD IgG Antibody Test Cassette	RPS/1138/2025	Self-declaration Others
FI-CEA-302	CEA Test Cassette	RPS/1138/2025	Self-declaration Others
FI-FOB-CT602	FOB Test Cassette	RPS/1138/2025	Self-declaration Others
FI-CTNT-402	cTnT Test Cassette	RPS/1138/2025	Self-declaration Others
FI-BHCG-302	Beta-HCG Test Cassette	RPS/1138/2025	Self-declaration Others
FI-T3-CT302	T3 Test Cassette	RPS/1138/2025	Self-declaration Others
FI-TES-CT302	TES Test Cassette	RPS/1138/2025	Self-declaration Others
FI-P4-CT302	P4 Test Cassette	RPS/1138/2025	Self-declaration Others
FI-FLU-502	Influenza A+B Test Cassette	RPS/1138/2025	Self-declaration Others
FI-RSV-502	RSV Test Cassette	RPS/1157/2025	Self-declaration Others
FI-DEN-402	Dengue IgG/IgM Test Cassette	RPS/1157/2025	Self-declaration Others
FI-DES-402	Dengue NS1 Test Cassette	RPS/1157/2025	Self-declaration Others
FI-IGE-402	IGE Test Cassette	RPS/1157/2025	Self-declaration Others
FI-FER-CT302	Ferritin Test Cassette	RPS/1157/2025	Self-declaration Others
FI-AMI-CT435	Troponin I/Myoglobin/CK-MB (3 in 1) Test Cassette	RPS/1157/2025	Self-declaration Others
FI-IL6-CT402	IL-6 Test Cassette	RPS/1157/2025	Self-declaration Others
FI-SAA-CT402	SAA Test Cassette	RPS/1157/2025	Self-declaration Others
FI-ASO-CT302	ASO Test Cassette	RPS/1157/2025	Self-declaration Others
FI-CSC-CT425	CRP/SAA Combo Test Cassette	RPS/1157/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
FI-ILPC-CT425	IL-6+PCT Combo Test Cassette	RPS/1157/2025	Self-declaration Others
FI-HBP-CT402	HBP Test Cassette	RPS/1157/2025	Self-declaration Others
FI-HBPC-CT425	HBP/PCT Combo Test Cassette	RPS/1157/2025	Self-declaration Others
FI-ST2-CT402	ST2 Test Cassette	RPS/1157/2025	Self-declaration Others
FI-LP-CT402	Lp-PLA2 Test Cassette	RPS/1157/2025	Self-declaration Others
FI-MPO-CT402	MPO Test Cassette	RPS/1157/2025	Self-declaration Others
FI-AMIT-CT435	Troponin T / Myoglobin / CK-MB Combo Test Cassette	RPS/1157/2025	Self-declaration Others
FI-CPC-CT435	Troponin I / NT-proBNP / D-Dimer Combo Test Cassette	RPS/1157/2025	Self-declaration Others
FI-COR-CT302	Cortisol Test Cassette	RPS/1157/2025	Self-declaration Others
FI-E2-CT302	Estradiol Test Cassette	RPS/1157/2025	Self-declaration Others
FI-FT4-CT302	FT4 Test Cassette	RPS/1157/2025	Self-declaration Others
FI-PRL-CT402	PRL Test Cassette	RPS/1157/2025	Self-declaration Others
FI-AMH-CT402	AMH Test Cassette	RPS/1157/2025	Self-declaration Others
FI-CDT-CT625	Clostridium difficile Toxin A/ toxin B Combo Test Cassette	RPS/1157/2025	Self-declaration Others
FI-CDG-CT602	Clostridium difficile GDH Test Cassette	RPS/1157/2025	Self-declaration Others
FI-AD-CT602	Adenovirus Antigen Test Cassette	RPS/1157/2025	Self-declaration Others
FI-SP-CT102	Streptococcus pneumoniae Test Cassette	RPS/1157/2025	Self-declaration Others
FI-LEG-CT102	Legionella pneumophila Test Cassette	RPS/1157/2025	Self-declaration Others
FI-SYP-CT402	Syphilis Test Cassette	RPS/1157/2025	Self-declaration Others
FI-ZI-CT402	Zika Antigen Test Cassette	RPS/1157/2025	Self-declaration Others
FI-ZIM-CT402	Zika IgM Test Cassette	RPS/1158/2025	Self-declaration Others
FI-CSG-CT402B	COVID-19 S-RBD IgG Quantitative Test Cassette	RPS/1158/2025	Self-declaration Others
FI-NCP-CT802	COVID-19 Antigen Test Cassette	RPS/1158/2025	Self-declaration Others
FI-CIC-CT525	COVID-19 Antigen/Influenza A+B Combo Test Cassette	RPS/1158/2025	Self-declaration Others
FI-RFM-CT402	Rheumatoid Factor IgM Test Cassette	RPS/1158/2025	Self-declaration Others
FI-CAL-CT602	Calprotectin Test Cassette	RPS/1158/2025	Self-declaration Others
FI-VD-CT302	Vitamin D Test Cassette	RPS/1158/2025	Self-declaration Others
FI-FFN-CT502	Fetal Fibronectin (fFN) Test Cassette	RPS/1158/2025	Self-declaration Others
FI-IGF-CT502	iGFBP-1 Test Cassette	RPS/1158/2025	Self-declaration Others
FI-CCP-CT402	Anti-CCP Test Cassette	RPS/1158/2025	Self-declaration Others
FI-CHI-CT402	Chikungunya IgG/IgM Test Cassette	RPS/1158/2025	Self-declaration Others
FI-FT3-CT302	FT3 Test Cassette	RPS/1158/2025	Self-declaration Others
FI-HP-CT602	H.pylori Antigen Test Cassette	RPS/1158/2025	Self-declaration Others
FI-MAL-CT435	Malaria P.f./P.v./Pan Test Cassette	RPS/1158/2025	Self-declaration Others
FI-TYP-CT402	Typhoid Test Cassette	RPS/1158/2025	Self-declaration Others
FI-CA211-CT402	CYFRA21-1 Test Cassette	RPS/1158/2025	Self-declaration Others
FI-T3-CT402	T3 Test Cassette	RPS/1158/2025	Self-declaration Others
FI-FT3-CT402	FT3 Test Cassette	RPS/1158/2025	Self-declaration Others
FI-T4-CT402	T4 Test Cassette	RPS/1158/2025	Self-declaration Others
FI-FT4-CT402	FT4 Test Cassette	RPS/1158/2025	Self-declaration Others
FI-FER-CT402	Ferritin Test Cassette	RPS/1158/2025	Self-declaration Others
FI-TSH-CT402	TSH Test Cassette	RPS/1158/2025	Self-declaration Others
FI-TET-CT402	Tetanus IgG Test Cassette	RPS/1158/2025	Self-declaration Others
FI-ROT-CT602	Rotavirus Test Cassette	RPS/1158/2025	Self-declaration Others
FI-IGA-CT402	IgA Test Cassette	RPS/1158/2025	Self-declaration Others
FI-VD-CT402	Vitamin D Test Cassette	RPS/1158/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
FI-AMP-CT102	AMP Test Cassette	RPS/1158/2025	Self-declaration Others
FI-BAR-CT102	BAR Test Cassette	RPS/1158/2025	Self-declaration Others
FI-BZO-CT102	BZO Test Cassette	RPS/1158/2025	Self-declaration Others
FI-COC-CT102	COC Test Cassette	RPS/1158/2025	Self-declaration Others
FI-MET-CT102	MET Test Cassette	RPS/1159/2025	Self-declaration Others
FI-MTD-CT102	MTD Test Cassette	RPS/1159/2025	Self-declaration Others
FI-OPI-CT102	OPI Test Cassette	RPS/1159/2025	Self-declaration Others
FI-THC-CT102	THC Test Cassette	RPS/1159/2025	Self-declaration Others
FI-APVP-CT102	APVP Test Cassette	RPS/1159/2025	Self-declaration Others
FI-MDMA-CT102	MDMA Test Cassette	RPS/1159/2025	Self-declaration Others
FI-MOP-CT102	MOP Test Cassette	RPS/1159/2025	Self-declaration Others
FI-DEC-CT435	Dengue IgG, IgM and NS1 Combo Test Cassette	RPS/1159/2025	Self-declaration Others
FI-CMC-CT475	Cardiac Markers Combo Test Cassette	RPS/1159/2025	Self-declaration Others
FI-BHCG-CT402	Beta-hCG Test Cassette (Whole Blood/Serum/Plasma)	RPS/1466/2025	Self-declaration Others
FI-HMPV-CT502	HMPV Test Cassette (Nasopharyngeal Swab)	RPS/1466/2025	Self-declaration Others
FI-AR-CT502	Adenovirus pneumoniae and RSV Combo Test Cassette (Nasopharyngeal Swab)	RPS/1466/2025	Self-declaration Others
FI-CD-CT602	Clostridium difficile GDH+Toxin A/B Test Cassette (Feces)	RPS/1466/2025	Self-declaration Others
FI-RAC-CT602	Rotavirus and Adenovirus Combo Test Cassette (Feces)	RPS/1466/2025	Self-declaration Others
FI-MXG-CT402	Monkeypox Virus Antigen Test Cassette	RPS/1466/2025	Self-declaration Others
FI-NOV-CT602	Norovirus Test Cassette (Feces)	RPS/1466/2025	Self-declaration Others
FI-MP-CT502	Mycoplasma pneumoniae Antigen Test Cassette (Throat Swab)	RPS/1466/2025	Self-declaration Others
FI-E2-CT402	Estradiol (E2) Test Cassette (Whole Blood/Serum/Plasma)	RPS/1466/2025	Self-declaration Others
FI-HPIV-CT502	HPIV Test Cassette (Nasopharyngeal Swab)	RPS/1466/2025	Self-declaration Others
FI-AD-CT502	Adenovirus pneumoniae Antigen Test Cassette (Nasopharyngeal Swab)	RPS/1466/2025	Self-declaration Others
FI-SHC-CT475	Sex hormones Combo Test Cassette	RPS/1159/2025	Self-declaration Others
FI-DOA-CT135~CT195	Multi-Drug x Drugs Test Cassette	RPS/1159/2025	Self-declaration Others
FCCRPCI	FIA Control-CRP	RPS/1166/2025	Self-declaration Others
FCPCTCI	FIA Control-PCT	RPS/1166/2025	Self-declaration Others
FCIL6CI	FIA Control-(IL-6)	RPS/1166/2025	Self-declaration Others
FCAFP	FIA Control-AFP	RPS/1166/2025	Self-declaration Others
FCCEACI	FIA Control-CEA	RPS/1173/2025	Self-declaration Others
FCFOBCI	FIA Control-FOB	RPS/1173/2025	Self-declaration Others
FCCTICI	FIA Control-cTnI	RPS/1173/2025	Self-declaration Others
FCCTNTCI	FIA Control-cTnT	RPS/1173/2025	Self-declaration Others
FCNBNPCI	FIA Control-(NT-proBNP)	RPS/1173/2025	Self-declaration Others
FCCKMBCI	FIA Control-(CK-MB)	RPS/1173/2025	Self-declaration Others
FCHFACI	FIA Control-(H-FABP)	RPS/1173/2025	Self-declaration Others
FCMYOCI	FIA Control-Myoglobin	RPS/1173/2025	Self-declaration Others
FCDDMCI	FIA Control-(D-Dimer)	RPS/1173/2025	Self-declaration Others
FCFSHCI	FIA Control-FSH	RPS/1173/2025	Self-declaration Others
FCLHCI	FIA Control-LH	RPS/1173/2025	Self-declaration Others
FCT3CI	FIA Control-T3	RPS/1173/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
FCFT3CI	FIA Control-FT3	RPS/1173/2025	Self-declaration Others
FCT4CI	FIA Control-T4	RPS/1173/2025	Self-declaration Others
FCFT4CI	FIA Control-FT4	RPS/1173/2025	Self-declaration Others
FCTESCI	FIA Control-Testosterone	RPS/1173/2025	Self-declaration Others
FCBHCGCI	FIA Control-(β -HCG)	RPS/1173/2025	Self-declaration Others
FCP4CI	FIA Control-Progesterone (P4)	RPS/1173/2025	Self-declaration Others
FCFERCI	FIA Control-Ferritin	RPS/1173/2025	Self-declaration Others
FCTSHCI	FIA Control-TSH	RPS/1173/2025	Self-declaration Others
FCAMHCI	FIA Control-AMH	RPS/1173/2025	Self-declaration Others
FCPRLCI	FIA Control-PRL	RPS/1173/2025	Self-declaration Others
FCCORCI	FIA Control-Cortisol	RPS/1173/2025	Self-declaration Others
FCALBCI	FIA Control-mAlb	RPS/1173/2025	Self-declaration Others
FCHBACI	FIA Control-HbA1c	RPS/1173/2025	Self-declaration Others
FCSTACI	FIA Control-Strep A	RPS/1173/2025	Self-declaration Others
FCFLUCI	FIA Control-FLU A+B	RPS/1173/2025	Self-declaration Others
FCRSVCI	FIA Control-RSV	RPS/1173/2025	Self-declaration Others
FCDESCI	FIA Control-Dengue NS1	RPS/1173/2025	Self-declaration Others
FCCICCI	FIA Control-COVID-19 Ag/Influenza A+B	RPS/1173/2025	Self-declaration Others
FCNCGCI	FIA Control-COVID-19 Antigen	RPS/1174/2025	Self-declaration Others
FCSYPCI	FIA Control-Syphilis	RPS/1174/2025	Self-declaration Others
FCHPGCI	FIA Control-H. pylori Antigen	RPS/1174/2025	Self-declaration Others
FCIGECI	FIA Control-IgE	RPS/1174/2025	Self-declaration Others
FCRFMCI	FIA Control-Rheumatoid Factor IgM	RPS/1174/2025	Self-declaration Others
FCCALCI	FIA Control-Calprotectin	RPS/1174/2025	Self-declaration Others
Rapid Test			
CBN-402	NT-proBNP Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CC-0203	Novel coronavirus Ag Rapid Test	RPS/1222/2025	Self-declaration Others
CCK-402/CCK-R402/CCK-R402SQ	CK-MB Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CCR-402/CCR-R402/CCR-R402Q/C CR-R402SQ	C-reactive protein Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CCR-T402/U402	C-reactive protein Semi-Quantitative Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CDM-402/CDM-R402/CDM-R402Q/CDM-R402SQ	D-dimer Rapid Test (WB/P)	RPS/1221/2025	Self-declaration Others
CFA-402	H-FABP Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CFC-425	H-FABP and cTnI Combo Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CMA-435	Myoglobin/CK-MB/Troponin I Combo Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CMA-445	H-FABP and Myoglobin/ CK-MB/ Cardiac Troponin I Combo Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CMY-402/CMY-R402/CMY-R402SQ	Myoglobin Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CNGL-CT402	NGAL Rapid Test Cassette	RPS/1223/2025	Self-declaration Others
COF-CT525H	COVID-19 and Flu A/B Multiplex Panel for Home Use (Nasal Swab)	RPS/1225/2025	Self-declaration Others
CPC-302/CPC-R302Q	Procalcitonin(PCT) Rapid Test (S/P)	RPS/1221/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
CPC-402/CPC-R402/CPC-R402Q/CP C-R402SQ	Procalcitonin(PCT) Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CTI-402/CTI-R402/CTI-R402SQ	cTnI Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
CTNT-402/CTNT-R402SQ	Cardiac Troponin T (cTnT) Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
DABP-102/114/101	AB-PINACA (ABP) Rapid Test (Urine)	RPS/1188/2025	Self-declaration Others
DAC-102/114/101	Acetaminophen (ACE) Rapid Test (Urine)	RPS/1188/2025	Self-declaration Others
DACL-102/114/101	7-Aminoclonazepam (7-ACL) Rapid Test (Urine)	RPS/1188/2025	Self-declaration Others
DAL-102/114/101	Alcohol (ALC) Rapid Test (Urine)	RPS/1188/2025	Self-declaration Others
DAL-801/802/803	Alcohol Rapid Test (Oral Fluid)	RPS/1190/2025	Self-declaration Others
DAL-902	Breath Alcohol Test With/Without blow bag (Breath)	RPS/1190/2025	Self-declaration Others
DALP-102/114/101	Alprazolam(ALP) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DAM-102/114/101	Amphetamine (AMP) Rapid Test (Urine)	RPS/1188/2025	Self-declaration Others
DAM-402	AMP Rapid Test (WB/S/P)	RPS/1215/2025	Self-declaration Others
DAM-802/803	Amphetamine (AMP) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DAM-H902	Amphetamine (AMP) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DAP-102/114/101	alpha-Pyrrolidinovalerophenone (alpha-PVP) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DAP-802/803	α-Pyrrolidinovalerophenone (α-PVP) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DAT-111	Adulteration Test(Urine)	RPS/1190/2025	Self-declaration Others
DBA-102/114/101	Barbiturate (BAR) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DBA-402	BAR Rapid Test (WB/S/P)	RPS/1215/2025	Self-declaration Others
DBA-802/803	Barbiturates (BAR) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DBA-H902	Barbiturate (BAR) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DBU-102/114/101	Buprenorphine (BUP) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DBU-402	BUP Rapid Test (WB/S/P)	RPS/1215/2025	Self-declaration Others
DBU-802/803	Buprenorphine (BUP) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DBU-H902	Buprenorphine (BUP) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DBZ-102/114/101	Benzodiazepines (BZO) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DBZ-402	BZO Rapid Test (WB/S/P)	RPS/1215/2025	Self-declaration Others
DBZ-802/803	Benzodiazepines (BZO) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DBZ-H902	Benzodiazepines (BZO) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DCA-102/114/101	Cathine (CAT) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DCAF-102/114/101	Caffeine (CAF) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DCAR-102/114/101	Carisoprodol(CAR) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DCCHOCI	Cholesterol Test Strip (3 in 1 test)	RPS/1174/2025	Self-declaration Others
DCFY-102/114/101	Carfentanyl(CFYL) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DCFY-802/803	Carfentanyl(CFYL) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DCIT-CT102/114/101	Citalopram (CIT) Rapid Test (Urine)	RPS/1222/2025	Self-declaration Others
DCL-102/114/101	Clonazepam (CLO) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
DCNB-102/114/101	Cannabinol (CNB) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DCO-102/114/101	COCAINE (COC) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DCO-402	COC Rapid Test (WB/S/P)	RPS/1215/2025	Self-declaration Others
DCO-802/803	COCAINE (COC) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DCO-H902	Cocaine (COC) Rapid Test(Hair)	RPS/1220/2025	Self-declaration Others
DCT-102/114/101	Cotinine (COT) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DCT-402	COT Rapid Test (WB/S/P)	RPS/1215/2025	Self-declaration Others
DCT-802/803	Cotinine (COT) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DCT-H902	Cotinine (COT) Rapid Test (Hair)	RPS/1220/2025	Self-declaration Others
DDI-102/114/101	Diazepam (DIA) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DED-102/114/101	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DED-402	EDDP Rapid Test (WB/S/P)	RPS/1215/2025	Self-declaration Others
DET-102/114/101	Ethyl Glucuronide (ETG) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DET-402	ETG Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DETO-CT102/114/101	Etomidate (ETO) Rapid Test (Urine)	RPS/1159/2025	Self-declaration Others
DFKE-CT102/114/101	Fluoketamine (FKET) Rapid Test (Urine)	RPS/1222/2025	Self-declaration Others
DFLX-102/114/101	Fluoxetine (FLX) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DFY-102/114/101	Fentanyl (FYL) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DFY-402	FYL Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DFY-802/803	Fentanyl (FYL) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DGAB-102/114/101	Gabapentin(GAB) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DGHB-102/CT114/CT101	gamma-Hydroxybutyric acid (GHB) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DGHB-CT114/101	γ -Hydroxybutyric acid (GHB) Rapid Test	RPS/1166/2025	Self-declaration Others
DKE-102/114/101	Ketamine (KET)Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DKE-402	KET Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DKE-802/803	Ketamine(KET) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DKE-H902	Ketamine (KET) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DKRA-102/114/101	Kratom(KRA) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DLS-102/114/101	Lysergic Acid Diethylamide (LSD) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DLS-402	LSD Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DMA-102/114/101	6-Monoacetylmorphine (6-MAM) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMA-802/803	6-Monoacetylmorphine (6-MAM) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DMA-H902	6-Monoacetylmorphine (6-MAM) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DMCA-102/114/101	Methcathinone(MCAT) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMD-102/114/101	Ecstasy (MDMA) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMD-402	MDMA Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DMD-802/803	Ecstasy (MDMA) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DMDA-102/114/101	Tenamfetamine (MDA) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMDA-402	MDA Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
DMD-H902	Ecstasy (MDMA) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DMDP-102/114/101	Methylenedioxypyrovalerone (MDPV) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMDP-402	MDPV Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DMDP-802/803	Methylenedioxypyrovalerone (MDPV) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DME-102/114/101	Methamphetamine (MET) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DME-402	MET Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DME-802/803	Methamphetamine (MET) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DME-H902	Methamphetamine (MET) Rapid Test (Hair)	RPS/1220/2025	Self-declaration Others
DMEP-102/114/101	Mephedrone HCl (MEP) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMES-102/114/101	Mescaline (MES) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DMO-102/114/101	Morphine (MOP) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DMO-402	MOP Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DMO-H902	Morphine (MOP) Rapid Test (Hair)	RPS/1220/2025	Self-declaration Others
DMP-102/114/101	Methylphenidate(MPD) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMPR-102/114/101	Meperidine (MPRD) Rapid Test (Urine)	RPS/1189/2025	Self-declaration Others
DMQ-102/114/101	Methaqualone (MQL) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DMT-102/114/101	Methadone (MTD) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DMT-402	MTD Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DMT-802/803	Methadone (MTD) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DMTZ-CT102/114/101	Desmethylnaltrexone(MTZ) Rapid Test (Urine)	RPS/1223/2025	Self-declaration Others
DNND-CT102/114/101	N,N-Dimethyltryptamine(NND) Rapid Test (Urine)	RPS/1223/2025	Self-declaration Others
DOA-125~1175 DOA-124~1204 DOA-127~1187	Multi-Drug X Drugs Rapid Test with/Without Adulteration(Urine)	RPS/1190/2025	Self-declaration Others
DOA-425~4175	Multi-drug Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DOA-H925~H9135	Multi-drug Rapid Test Cassette (Hair)	RPS/1220/2025	Self-declaration Others
DOP-102/114/101	Opiates (OPI) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DOP-802/803	Opiates (OPI) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DOX-102/114/101	Oxycodone (OXY) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DOX-402	OXY Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DOX-802/803	Oxycodone (OXY) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DOX-H902	Oxycodone (OXY) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DOZP-102/114/101	Olanzapine (OZP) Rapid Test Cassette (Urine)	RPS/1190/2025	Self-declaration Others
DPAP-102/114/101	Papaverine (PAP) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DPC-102/114/101	Phencyclidine (PCP) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DPC-402	PCP Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DPC-802/803	Phencyclidine (PCP) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DPC-H902	Phencyclidine (PCP) Rapid Test (Hair)	RPS/1222/2025	Self-declaration Others
DPG-102/114/101	Pregabalin (PGB) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DPG-CT802/803	Pregabalin (PGB) Rapid Test (Oral Fluid)	RPS/1159/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
DPP-102/114/101	Propoxyphene (PPX) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DPP-402	PPX Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DPY-CT102/114/101	Psilocybin (PY) Rapid Test (Urine)	RPS/1159/2025	Self-declaration Others
DQTP-102/114/101	Quetiapine(QTP) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DRPD-CT102/114/101	Risperidone(RPD) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DSC-CT102/114/101	Scopolamine (SCOP) Rapid Test (Urine)	RPS/1223/2025	Self-declaration Others
DSD-823~8123 DSD-825~895 DSD-827~8167	Multi-Drug Rapid Test(Oral Fluid)	RPS/1215/2025	Self-declaration Others
DSM-102/114/101	Synthetic Marijuana (K2) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DSM-402	K2 Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DSM-802/803	Synthetic Marijuana (K2) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DTAP-CT102/114/101	Tapentadol (TAP) Rapid Test (Urine)	RPS/1223/2025	Self-declaration Others
DTC-102/114/101	Tricyclic Antidepressants (TCA) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DTC-402	TCA Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DTH-102/114/101	Marijuana (THC) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DTH-402	THC Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DTH-P802/803	Marijuana (THC) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DTLD-102/114/101	Tilidine (TLD) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DTM-102/114/101	Tramadol (TML) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DTM-402	TML Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
DTM-802/803	Tramadol(TML) Rapid Test (Oral Fluid)	RPS/1215/2025	Self-declaration Others
DTRO-102/114/101	Tropicamide(TRO)Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DTZD-102/114/101	Trazodone(TZD) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DUR-102/114/101	UR-144 Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DXYL-CT102/114/101	Xylazine(XYL) Rapid Test (Urine)	RPS/1159/2025	Self-declaration Others
DZAL-102/114/101	Zaleplon(ZAL) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DZO-102/114/101	Zolpidem(ZOL) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
DZOP-102/114/101	Zopiclone(ZOP) Rapid Test (Urine)	RPS/1190/2025	Self-declaration Others
FAMH-402/FAMH-R402Q	AMH Rapid Test (WB/S/P)	RPS/1175/2025	Self-declaration Others
FFF-502	Fetal Fibronectin (fFN) Rapid Test (Vaginal Secretion)	RPS/1175/2025	Self-declaration Others
FFS-101/102/103	FSH Rapid Test(Urine)	RPS/1175/2025	Self-declaration Others
FHC-101/102/103/111, FHC-F103	Pregnancy (hCG) Rapid Test (Urine)	RPS/1175/2025	Self-declaration Others
FHC-201/202/211, FHC-U201/202/211	Pregnancy (hCG) Rapid Test(S/P/U)	RPS/1175/2025	Self-declaration Others
FHC-CTE103H	Digital HCG Pregnancy Test	RPS/1222/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
FHC-U101/U102/ U103/U111	Pregnancy (hCG) Enhanced Sensitivity Rapid Test	RPS/1175/2025	Self-declaration Others
FIG-501/FIG-502	Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test (Vaginal Secretion)	RPS/1175/2025	Self-declaration Others
FLH-101/102/103/ 111,FLH-M103	Ovulation (LH) Rapid Test(Urine)	RPS/1175/2025	Self-declaration Others
FVMT-CT562	Vaginal Secretion Rapid Test (Vaginal Swab)	RPS/1223/2025	Self-declaration Others
IAD-502	Adenovirus pneumoniae Antigen Rapid Test (Swab)	RPS/1187/2025	Self-declaration Others
IAD-602	Adenovirus Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
IAD-CT607	Adenovirus Rapid Test (Feces)	RPS/1159/2025	Self-declaration Others
IARC-525	Adenovirus&RSV Combo Rapid Test (Nasopharyngeal Swab)	RPS/1187/2025	Self-declaration Others
IARI-535	Adenovirus, RSV and Influenza A+B Combo Rapid Test (Swab)	RPS/1187/2025	Self-declaration Others
IAS-602/IAS-607	Astrovirus Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
IBA-402	Brucella Abortus Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma)	RPS/1222/2025	Self-declaration Others
ICA-502	Candida Albicans Rapid Test (Vaginal Secretion)	RPS/1175/2025	Self-declaration Others
ICAM-602	Campylobacter Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
ICAM-CT607	Campylobacter Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
ICD-635B	Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
ICD-CT637	Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
ICDG-602	Clostridium difficile GDH Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
ICDT-625B	Clostridium difficile Toxin A +Toxin B Combo Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
ICGC-625	Cryptosporidiumand Giardia Lamblia Combo Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
ICHA-302	Chagas Rapid Test (S/P)	RPS/1186/2025	Self-declaration Others
ICHA-402	Chagas Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
ICHI-302	Chikungunya IgG/IgM Rapid Test (S/P)	RPS/1186/2025	Self-declaration Others
ICHI-402	Chikungunya IgG/IgM Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
ICIC-525	COVID-19 and Influenza A+B Antigen Combo Rapid Test (Nasopharyngeal Swab)	RPS/1188/2025	Self-declaration Others
ICN-CT402	SARS-CoV-2 Neutralization Antibody Rapid Test	RPS/1188/2025	Self-declaration Others
ICNP-CT402	COVID-19 Nucleocapsid Protein Antibody Rapid Test	RPS/1222/2025	Self-declaration Others
ICO-CTP50	SARS-COV-2 RT-qPCR Assay	RPS/1225/2025	Self-declaration Others
ICOV-502/ INCP-CTR502	COVID-19 Antigen Rapid Test (Swab)	RPS/1187/2025	Self-declaration Others
ICR-602	Cryptosporidium Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
ICRG-402	Cryptococcus Antigen Rapid Test (WB/S/P/CSF)	RPS/1187/2025	Self-declaration Others
ICS-CT402	SARS-CoV-2 S-RBD Antibody Rapid Test	RPS/1188/2025	Self-declaration Others
ICSG-CT402	SARS-CoV-2 S-RBD IgG Antibody Rapid	RPS/1188/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
	Test		
IDCZ-CT435	Dengue/Chikungunya/Zika Combo Rapid Test Cassette (WB/S/P)	RPS/1166/2025	Self-declaration Others
IDEC-425	Dengue IgG/IgM And NS1 Combo Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
IDEN-402	Dengue IgG/IgM Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
IDES-402	Dengue NS1 Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
IDZC-CT445	Dengue/Zika/Chikungunya Combo Rapid Test Cassette (WB/S/P)	RPS/1166/2025	Self-declaration Others
IECA-CT402	EBV VCA IgA Rapid Test Cassette (Whole Blood/Serum/Plasma)	RPS/1222/2025	Self-declaration Others
IECG-402	EBV VCA IgG Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
IECG-425	EBV VCA and EBNA IgG Combo Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
IEGC-602	Entamoeba/Giardia/Crypto Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
IEGC-602/IEGC-635	Entamoeba/Giardia/Crypto Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
IEGC-635	Entamoeba/Giardia/Crypto Combo Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
IEH-602	Entamoeba Histolytica Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
IENG-402	EBNA IgG Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
IEVM-CT402	EV71 IgM Antibody Rapid Test (Whole Blood/Serum/Plasma)	RPS/1222/2025	Self-declaration Others
IFA-502/501	H1N1 Rapid Test (Swab)	RPS/1188/2025	Self-declaration Others
IFIL-302	Filariasis IgG/IgM Rapid Test (S/P)	RPS/1186/2025	Self-declaration Others
IFIL-402	Filariasis IgG/IgM Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
IFLA-501/IFLA-502	Influenza A Rapid Test (Swab/Nasal Aspirate)	RPS/1187/2025	Self-declaration Others
IGL-602	Giardia Lamblia Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
IGO-502	Gonorrhea Rapid Test (Swab)	RPS/1175/2025	Self-declaration Others
IHA-302	HAV IgM Rapid Test (S/P)	RPS/1187/2025	Self-declaration Others
IHA-402	HAV IgM Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
IHAGM-325	HAV IgG/IgM Combo Rapid Test (S/P)	RPS/1187/2025	Self-declaration Others
IHAGM-425	HAV IgG/IgM Combo Rapid Test Cassette (WB/S/P)	RPS/1187/2025	Self-declaration Others
IHE-302	HEV IgG/IgM Rapid Test (S/P)	RPS/1187/2025	Self-declaration Others
IHMPV-CT502	HMPV Rapid Test (Nasopharyngeal Swab)	RPS/1166/2025	Self-declaration Others
IHP-302	H. pylori Antibody Rapid Test (S/P)	RPS/1186/2025	Self-declaration Others
IHP-402	H. pylori Antibody Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
IHP-602	H. pylori Antigen Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
IHP-CT607	H. pylori Antigen Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
IHVGM-CT402	Hantavirus IgG/IgM Rapid Test Cassette	RPS/1223/2025	Self-declaration Others
IIN-501/IIN-502	Influenza A+B Rapid Test (Swab/Nasal Aspirate)	RPS/1187/2025	Self-declaration Others
IINA-525	Influenza A/B +H1N1 Combo Rapid Test (Swab)	RPS/1188/2025	Self-declaration Others
ILEG-102	Legionella pneumophila Rapid Test (Urine)	RPS/1188/2025	Self-declaration Others
ILEI-402	Leishmania IgG/IgM Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
ILEP-402	Leptospira IgG/IgM Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
ILY-402	Lyme IgG/IgM Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
IMA-402	Malaria P.f. Rapid Test (WB)	RPS/1187/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
IME-CT402	Measles IgG/IgM Rapid Test (WB/S/P)	RPS/1166/2025	Self-declaration Others
IMEG-CT402	Measles IgG Antibody Rapid Test (Whole Blood/Serum/Plasma)	RPS/1222/2025	Self-declaration Others
IMO-402	MONO Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
IMP-425	Mycoplasma pneumoniae IgG/IgM Combo Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
IMP-502	Mycoplasma pneumoniae Antigen Rapid Test (Swab)	RPS/1187/2025	Self-declaration Others
IMPM-402	Mycoplasma Pneumoniae IgM Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
IMPN-402	Malaria P.f./ Pan Rapid Test (WB)	RPS/1187/2025	Self-declaration Others
IMPV-402	Malaria P.f./P.v. Rapid Test (WB)	RPS/1187/2025	Self-declaration Others
IMPVF-402	Malaria P.f./P.v./Pan Rapid Test Cassette (Whole Blood)	RPS/1222/2025	Self-declaration Others
IMVD-645	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
IMVD-CT647	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
IMXB-CT402	Monkeypox Virus Antibody Rapid Test(WB/S/P)	RPS/1188/2025	Self-declaration Others
IMXG-CT402	Monkeypox Virus Antigen Rapid Test(WB/S/P)	RPS/1188/2025	Self-declaration Others
INCP-402/INCP-402B	2019-nCoV IgG/IgM Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
INCP-402S	2019-nCoV IgG/IgM Rapid Test Singles Use Kit (WB)	RPS/1187/2025	Self-declaration Others
INCP-411A/INCP-411B/ICOV-402/I COV-411/INCP-C TR402	COVID-19 IgG/IgM Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
INCP-CT501	COVID-19 Antigen Rapid Test Strip (Nasopharyngeal Swab)	RPS/1188/2025	Self-declaration Others
INCP-CT802	COVID-19 Antigen Rapid Test (Oral fluid)	RPS/1188/2025	Self-declaration Others
INCP-CT803	SARS-CoV-2(COVID-19) Antigen Rapid Test (Oral Fluid)	RPS/1222/2025	Self-declaration Others
INCPG-402/411	COVID-19 IgG Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
INMC-425	COVID-19 and M.pneumoniae IgG/IgM Combo Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
INMCG-425	COVID-19 and M.pneumoniae IgG Combo Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
INO-602	Norovirus Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
INO-CT607	Norovirus Rapid Test (Feces)	RPS/1159/2025	Self-declaration Others
INRA-635	Norovirus, Rotavirus and Adenovirus Combo Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
INRA-CT637	Norovirus, Rotavirus and Adenovirus Combo Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
IPIV-CT502	HPIV Rapid Test (Nasopharyngeal Swab)	RPS/1166/2025	Self-declaration Others
IRAC-625	Rotavirus and Adenovirus Combo Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
IRAC-CT627	Rotavirus and Adenovirus Combo Rapid Test (Feces)	RPS/1159/2025	Self-declaration Others
IRIC-525	RSV&Influenza A+B Combo Rapid Test (Swab/Nasal Aspirate)	RPS/1187/2025	Self-declaration Others
IRO-602	Rotavirus Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
IRO-CT607	Rotavirus Rapid Test (Feces)	RPS/1159/2025	Self-declaration Others
IRS-502	RSV Rapid Test (Nasopharyngeal)	RPS/1187/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
	swab/Nasal Aspirate)		
IRT- CT545	SARS-CoV-2/Influenza A+B/RSV/Adenovirus Antigen Combo Rapid Test	RPS/1188/2025	Self-declaration Others
IRT- CT555	SARS-CoV-2/Influenza A+B/RSV/Adenovirus/M.pneumoniae Antigen Combo Rapid Test	RPS/1188/2025	Self-declaration Others
IRT9-CT555/ IRTC-CT5X5	Multiplex Respiratory Antigen Rapid Test (Swab)	RPS/1466/2025	Self-declaration Others
IRTA-CT545	Adenovirus/RSV/HMPV/Influenza A+B Combo Rapid Test (Nasopharyngeal Swab)	RPS/1166/2025	Self-declaration Others
IRTA-CT555	Adenovirus/RSV/HMPV/SARS-CoV-2/Influenza A+B Combo Rapid Test (Nasopharyngeal Swab)	RPS/1166/2025	Self-declaration Others
IRTB-CT555	Adenovirus/RSV/HMPV/HPIV/Influenza A+B Combo Rapid Test (Nasopharyngeal Swab)	RPS/1166/2025	Self-declaration Others
ISB-501/ ISB-502	Strep B Rapid Test (Swab)	RPS/1175/2025	Self-declaration Others
ISG-302	HSV 1/2 IgG Rapid Test (S/P)	RPS/1175/2025	Self-declaration Others
ISG-402	HSV 1/2 IgG Rapid Test (WB/S/P)	RPS/1175/2025	Self-declaration Others
ISGM-302	HSV 1/2 IgG/IgM Rapid Test (S/P)	RPS/1175/2025	Self-declaration Others
ISGM-402	HSV 1/2 IgG/IgM Rapid Test (WB/S/P)	RPS/1175/2025	Self-declaration Others
ISGMA-CT402	HSV 1 IgG/IgM Rapid Test Cassette	RPS/1223/2025	Self-declaration Others
ISGMB-CT402	HSV 2 IgG/IgM Rapid Test Cassette	RPS/1223/2025	Self-declaration Others
ISH-CT625	Shigella Rapid Test Cassette (Feces)	RPS/1222/2025	Self-declaration Others
ISH-CT627	Shigella Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
ISHF-CT602	Shigella Flexneri Antigen Rapid Test Cassette (Feces)	RPS/1160/2025	Self-declaration Others
ISHF-CT607	Shigella Flexneri Antigen Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
ISHS-CT602	Shigella Sonnei Antigen Rapid Test Cassette (Feces)	RPS/1160/2025	Self-declaration Others
ISHS-CT607	Shigella Sonnei Antigen Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
ISIC-CT502	SARS-CoV-2 and Influenza A+B Antigen Combo Rapid Test (Swab)	RPS/1166/2025	Self-declaration Others
ISIR-CT535	SARS-CoV-2/Influenza A+B/RSV Antigen Combo Rapid Test	RPS/1188/2025	Self-declaration Others
ISLC-125	Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test (Urine)	RPS/1187/2025	Self-declaration Others
ISM-302	HSV 1/2 IgM Rapid Test (S/P)	RPS/1175/2025	Self-declaration Others
ISM-402	HSV 1/2 IgM Rapid Test (WB/S/P)	RPS/1175/2025	Self-declaration Others
ISP-102	Streptococcus pneumoniae Antigen Rapid Test (Urine)	RPS/1187/2025	Self-declaration Others
ISPT-602	Salmonella paratyphi Antigen Rapid Test Cassette (Feces)	RPS/1186/2025	Self-declaration Others
ISPT-CT607	Salmonella paratyphi Antigen Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
IST-501/IST-502	Strep A Rapid Test (Control Line in Red)(Throat Swab)	RPS/1188/2025	Self-declaration Others
ISTB-501/ISTB-502	Strep A Rapid Test (Control Line in Blue)(Throat Swab)	RPS/1188/2025	Self-declaration Others
ISTP-625	Salmonella typhi and paratyphi Antigen Combo Rapid Test Cassette (Feces)	RPS/1186/2025	Self-declaration Others
ISTPB-CT625	Salmonella typhi and paratyphi B Antigen Combo Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
ISTPB-CT627	Salmonella typhi and paratyphi B Antigen Combo Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
ISTP-CT627	Salmonella typhi and paratyphi Antigen Combo Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
ISTY-602	Salmonella Typhi Antigen Rapid Test (Feces)	RPS/1186/2025	Self-declaration Others
ISTY-CT607	Salmonella Typhi Antigen Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
ISY-301/ ISY-302	Syphilis Rapid Test (S/P)	RPS/1187/2025	Self-declaration Others
ISY-401/ISY-402	Syphilis Rapid Test (WB/S/P)	RPS/1187/2025	Self-declaration Others
ITB-402	Tuberculosis (TB) Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
ITE-402/ITE-R402 SQ	Tetanus Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
ITSU-402	Scrub Typhus IgG/IgM Rapid Test (WB/S/P)	RPS/1188/2025	Self-declaration Others
ITV-502	Trichomonas Vaginalis Rapid Test (Vaginal Swab)	RPS/1175/2025	Self-declaration Others
ITY-402	Typhoid Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
ITYG-CT402	Typhoid IgG Rapid Test Cassette (WB/S/P)	RPS/1166/2025	Self-declaration Others
ITYM-CT402	Typhoid IgM Rapid Test Cassette (WB/S/P)	RPS/1166/2025	Self-declaration Others
IVCA-602	Vibrio cholerae O1 (VC O1) Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
IVCAB-625	Vibrio cholerae O1/O139 Combo Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
IVCAB-CT627	Vibrio cholerae O1/O139 Combo Rapid Test (Feces)	RPS/1160/2025	Self-declaration Others
IVCAI-CT602	Vibrio Cholera O1 Inaba (VC O1 Inaba) Rapid Test Cassette (Feces)	RPS/1223/2025	Self-declaration Others
IVCAO-CT602	Vibrio Cholera O1 Ogawa (VC O1 Ogawa) Rapid Test Cassette (Feces)	RPS/1223/2025	Self-declaration Others
IVCB-602	Vibrio cholerae O139 (VC O139) Rapid Test (Feces)	RPS/1175/2025	Self-declaration Others
IVPH-504	Vaginal pH Rapid Test (Vaginal Secretion)	RPS/1175/2025	Self-declaration Others
IVZM-CT402	Varicella Zoster Virus IgM Rapid Test (Whole Blood/Serum/Plasma)	RPS/1222/2025	Self-declaration Others
IZIB-402	Zika IgG/IgM Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
IZIC-425	Zika IgG/IgM and NS1 Combo Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
IZIG-402	Zika NS1 Rapid Test (WB/S/P)	RPS/1186/2025	Self-declaration Others
OAL-901	Breast Milk Alcohol Rapid Test Dipstick	RPS/1223/2025	Self-declaration Others
OBS-901/902	Blood Stain Rapid Test (Stain)	RPS/1221/2025	Self-declaration Others
OCAL-602/OCAL-R602 Q	Calprotectin test (Feces)	RPS/1221/2025	Self-declaration Others
OCAL-CT607	Calprotectin Rapid test	RPS/1166/2025	Self-declaration Others
OCEA-CT402	Celiac Rapid Test Cassette (Whole Blood/Serum/Plasma)	RPS/1223/2025	Self-declaration Others
OCSC-425	SAA and CRP Combo Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
ODME-CT402	Dust Mite IgE Rapid Test Cassette	RPS/1223/2025	Self-declaration Others
OFE-402/OFE-R40 2Q	Ferritin Rapid test (WB/S/P)	RPS/1221/2025	Self-declaration Others
OFE-T402	Ferritin Semi-Quantitative Rapid test (WB/S/P)	RPS/1221/2025	Self-declaration Others
OHA-402	HbA1c Rapid Test	RPS/1222/2025	Self-declaration Others
OHBS-CT411	HB Hemoglobin Test Strip	RPS/1223/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
OHS-901/902	Human Semen Rapid Test (Stain)	RPS/1221/2025	Self-declaration Others
OIBD-625	Calprotectin and Lactoferrin Combo Rapid Test (Feces)	RPS/1221/2025	Self-declaration Others
OIBD-CT627	Calprotectin and Lactoferrin Combo Rapid Test	RPS/1166/2025	Self-declaration Others
OIGE-402	IgE Rapid Test Cassette (WB/S/P)	RPS/1221/2025	Self-declaration Others
OIL-CT402	IL-6 Rapid Test (Whole Blood/ Serum/ Plasma)	RPS/1223/2025	Self-declaration Others
OLF-602	Lactoferrin Rapid test (Feces)	RPS/1221/2025	Self-declaration Others
OLF-CT607	Lactoferrin Rapid test	RPS/1166/2025	Self-declaration Others
OMAL-101/102	Micro-Albumin Qualitative Rapid Test (Urine)	RPS/1221/2025	Self-declaration Others
OMIA-101/102	Micro-Albumin Semi-Quantitative Rapid Test (Urine)	RPS/1221/2025	Self-declaration Others
ORF-302	Rheumatoid Factor Rapid Test (S/P)	RPS/1221/2025	Self-declaration Others
OSA-402	SAA Rapid Test (WB/S/P)	RPS/1221/2025	Self-declaration Others
OSC-902	Sperm Concentration Rapid Test (Sperm)	RPS/1222/2025	Self-declaration Others
OSP-902	SP-10 Male Fertility Rapid Test	RPS/1222/2025	Self-declaration Others
OTS-402/OTS-R40 2Q/OTS-R402SQ	TSH Rapid Test (WB/S/P)	RPS/1222/2025	Self-declaration Others
OVD-402/OVD-R 402SQ	Vitamin D Rapid Test (WB)	RPS/1222/2025	Self-declaration Others
T125-402	CA125 Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
T153-402	CA15-3 Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
T199-402	CA19-9 Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
TAF-402	AFP Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
TCE-402	CEA Rapid Test (WB/S/P)	RPS/1220/2025	Self-declaration Others
TCFC-625	Calprotectin and FOB Combo Rapid Test (Feces)	RPS/1220/2025	Self-declaration Others
TCTBP-CT647	Calprotectin/Transferrin/FOB/Hb-Hp Combo Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
TCTF-CT627	Transferrin/FOB and Calprotectin Combo Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
TFO-602/TFO-R60 2/TFO-R602Q/TF O-R602SQ	FOB Rapid Test (Feces)	RPS/1220/2025	Self-declaration Others
TFO-CT607	FOB Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
THPB-625	Hb + Hb-Hp Combo Rapid Test (Feces)	RPS/1221/2025	Self-declaration Others
THPV-CT502	HPV Antigen Rapid Test Cassette (Cervical Swab)	RPS/1166/2025	Self-declaration Others
TNMP-CT102	NMP22 Antigen Rapid Test	RPS/1223/2025	Self-declaration Others
TTFC-625	Transferrin and FOB Combo Rapid Test (Feces)	RPS/1221/2025	Self-declaration Others
TTFC-CT607	Transferrin/FOB Combo Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
TTFH-635	Transferrin/FOB and Hb-Hp Combo Rapid Test (Feces)	RPS/1221/2025	Self-declaration Others
TTFH-CT627	Transferrin/FOB and Hb-Hp Combo Rapid Test (Feces)	RPS/1166/2025	Self-declaration Others
Standard Control			
SCADE-D-L	Adenovirus Control	RPS/1223/2025	Self-declaration Others
SCADE-S	Adenovirus pneumoniae Antigen Control	RPS/1224/2025	Self-declaration Others
SCAFP-D-L	AFP Control	RPS/1225/2025	Self-declaration Others
SCARC-S	Adenovirus + RSV Control	RPS/1224/2025	Self-declaration Others
SCARI-S	Adenovirus/RSV/Influenza A+B Control	RPS/1224/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
SCAS-D-L	Astrovirus Control (Powder and Liquid)	RPS/1224/2025	Self-declaration Others
SCBA-L	Brucella Abortus Control	RPS/1224/2025	Self-declaration Others
SCBNP-L	NT-proBNP Control	RPS/1225/2025	Self-declaration Others
SCBS-D-L	Blood Stain Control	RPS/1225/2025	Self-declaration Others
SCCA-D-L	Candida Albicans Control	RPS/1224/2025	Self-declaration Others
SCCAL-D-L	Calprotectin Control	RPS/1225/2025	Self-declaration Others
SCCAM-D-L	Campylobacter Control	RPS/1224/2025	Self-declaration Others
SCCD-D-L	Clostridium difficile GDH + Toxin A + Toxin B Control	RPS/1223/2025	Self-declaration Others
SCCDG-D-L	Clostridium difficile GDH Control	RPS/1223/2025	Self-declaration Others
SCCDT-D-L	Clostridium difficile Toxin A+ Toxin B Control	RPS/1223/2025	Self-declaration Others
SCCEA-D-L	CEA Control	RPS/1225/2025	Self-declaration Others
SCCIC-S	COVID-19 and Influenza A+B Antigen Combo Control	RPS/1224/2025	Self-declaration Others
SCCK-D	CK-MB Control	RPS/1225/2025	Self-declaration Others
SCCOV-D-L	COVID-19 AG CONTROL	RPS/1222/2025	Self-declaration Others
SCCOV-D-L	COVID-19 Ag control (Swab)	RPS/1222/2025	Self-declaration Others
SCCRP-D	CRP Control	RPS/1225/2025	Self-declaration Others
SCCRY-L	Cryptosporidium Control	RPS/1225/2025	Self-declaration Others
SCCTNI-L	Cardiac Troponin I Control	RPS/1225/2025	Self-declaration Others
SCDEN-D	Dengue NS1 Control (Powder)	RPS/1224/2025	Self-declaration Others
SCDEN-D-L	Dengue NS1 Control (Powder and Liquid)	RPS/1224/2025	Self-declaration Others
SCDEN-L	Dengue NS1 Control (Liquid)	RPS/1224/2025	Self-declaration Others
SCDM-D	D-dimer Control	RPS/1225/2025	Self-declaration Others
SCEH-D-L	Entamoeba Histolytica Control	RPS/1225/2025	Self-declaration Others
SCFAB-D	H-FABP Control	RPS/1225/2025	Self-declaration Others
SCFERR-D	Ferritin Control	RPS/1223/2025	Self-declaration Others
SCFFN-D-L	fFN Control	RPS/1223/2025	Self-declaration Others
SCFLAB-S	Influenza A+B Control	RPS/1224/2025	Self-declaration Others
SCFLA-S	Influenza A Control	RPS/1224/2025	Self-declaration Others
SCFOB-D-L	Fecal Occult Blood (FOB) Control	RPS/1225/2025	Self-declaration Others
SCGL-D-L	Giardia Lamblia Control	RPS/1224/2025	Self-declaration Others
SCGON-S	Gonorrhea Control	RPS/1223/2025	Self-declaration Others
SCHB-S-CT	HB Hemoglobin Control Strip	RPS/1225/2025	Self-declaration Others
SCHCG-D	HCG Control	RPS/1223/2025	Self-declaration Others
SCHPB-L	H. pylori Antibody Control	RPS/1224/2025	Self-declaration Others
SCHPG-D-L	H. pylori Antigen Control (Powder and Liquid)	RPS/1224/2025	Self-declaration Others
SCHS-L	Human Semen Control	RPS/1225/2025	Self-declaration Others
SCIBD-D-L	Calprotectin/Lactoferrin Control	RPS/1225/2025	Self-declaration Others
SCIGF-D-L	iGFBP-1 Control	RPS/1223/2025	Self-declaration Others
SCMCT-L	Myoglobin/CK-MB/Troponin I Combo Control	RPS/1225/2025	Self-declaration Others
SCMONO-L	MONO Control	RPS/1224/2025	Self-declaration Others
SCMPF-D	Malaria P.f. Control	RPS/1224/2025	Self-declaration Others
SCMPN-D	Malaria P.f./ Pan Control	RPS/1224/2025	Self-declaration Others
SCMP-S	Mycoplasma Pneumoniae Antigen Control	RPS/1224/2025	Self-declaration Others
SCMPV-D	Malaria P.f./P.v. Control	RPS/1224/2025	Self-declaration Others
SCMPVF-D	Malaria P.f./P.v./Pan Control	RPS/1224/2025	Self-declaration Others
SCMYO-D	Myoglobin Control	RPS/1225/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
SCNOR-D-L	Norovirus Control	RPS/1223/2025	Self-declaration Others
SCPCT-D	PCT Control	RPS/1225/2025	Self-declaration Others
SCRAC-D-L	Adenovirus/Rotavirus Control	RPS/1224/2025	Self-declaration Others
SCROT-D-L	Rotavirus Control	RPS/1223/2025	Self-declaration Others
SCRSV-S	RSV Control	RPS/1224/2025	Self-declaration Others
SCSP-L	Streptococcus pneumoniae Control	RPS/1225/2025	Self-declaration Others
SCSTA-L	Strep A Control	RPS/1224/2025	Self-declaration Others
SCSTB-L	Strep B Control	RPS/1223/2025	Self-declaration Others
SCSTY-D	Salmonella typhi Antigen Control	RPS/1224/2025	Self-declaration Others
SCSYP-L	Syphilis (SYP) Control	RPS/1224/2025	Self-declaration Others
SCTB-L	Tuberculosis Control	RPS/1224/2025	Self-declaration Others
SCTSH-D-L	TSH Control	RPS/1225/2025	Self-declaration Others
SCTV-D-L	Trichomonas Vaginalis Control	RPS/1224/2025	Self-declaration Others
SCZIG-D	Zika NS1 Control	RPS/1224/2025	Self-declaration Others
Chemiluminescence Test			
CI-AFP-CT	Alpha-fetoprotein (AFP) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-AMH-CT	Anti-mullerian Hormone (AMH) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-BNP-CT	Brain Natriuretic Peptide (BNP) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CA125-CT	Cancer Antigen 125 (CA125) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CA153-CT	Cancer Antigen 15-3 (CA15-3) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CA199-CT	Carbohydrate Antigen 199 (CA19-9) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CA242-CT	Cancer Antigen 242 (CA242) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CA724-CT	Cancer Antigen 72-4 (CA72-4) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CEA-CT	Carcinoembryonic Antigen (CEA) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CKMB-CT	Creatine Kinase MB (CKMB) Test Kit (CLIA)	RPS/1225/2025	Self-declaration Others
CI-CPE-CT	C-Peptide (CP) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CRP-CT	C-reactive Protein (CRP) Test Kit (CLIA)	RPS/1225/2025	Self-declaration Others
CI-CTI-CT	Cardiac Troponin-I (cTnI) Test Kit (CLIA)	RPS/1225/2025	Self-declaration Others
CI-CTNT-CT	Cardiac Troponin-T (cTnT) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-CYFRA211-CT	Cytokeratin-19-fragment (CYFRA21-1) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-DDM-CT	D-Dimer Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-E2-CT	Estradiol (E2) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-FA-CT	Folic Acid (FA) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-FER-CT	Ferritin Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-FSH-CT	FSH Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-FT3-CT	Free Triiodothyronine (FT3) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-FT4-CT	Free Thyroxine (FT4) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-G17-CT	Gastrin 17 (G-17) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-HBA-CT	Glycated Hemoglobin (HbA1c) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-HE4-CT	Human Epididymis Protein 4 (HE4) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others

EC Declaration of Conformity
Version 1.0

Cat.no.	Product Name	Certificate No.	Classification under IVDD
CI-HFABP-CT	Heart-fatty Acid-binding Protein (H-FABP) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-HPG-CT	Helicobacter pylori (HP) IgG Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-IL6-CT	Interleukin-6(IL-6) Test Kit (CLIA)	RPS/1225/2025	Self-declaration Others
CI-INS-CT	Insulin (INS) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-LH-CT	LH Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-MYO-CT	Myoglobin (MYO) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-NBNP-CT	N-Terminal pro-B-type Natriuretic Peptide (NT-proBNP) Test Kit (CLIA)	RPS/1225/2025	Self-declaration Others
CI-NSE-CT	Neuron-specific Enolase (NSE) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-PCT-CT	Procalcitonin (PCT) Test Kit (CLIA)	RPS/1225/2025	Self-declaration Others
CI-PG I -CT	Pepsinogen I (PG I) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-PG II -CT	Pepsinogen II (PG II) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-PGRP-CT	Gastrin Releasing Peptide Precursor (ProGRP) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-PRL-CT	Prolactin Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-PROG-CT	Progesterone Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-SAA-CT	Serum Amyloid A Protein (SAA) Test Kit (CLIA)	RPS/1225/2025	Self-declaration Others
CI-SCC-CT	Squamous Cell Carcinoma Antigen (SCC) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-sST2-CT	Growth Stimulation Expressed Gene 2 (ST2) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-T3-CT	Triiodothyronine (T3) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-T4-CT	Thyroxine (T4) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-TES-CT	Testosterone Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-TGAb-CT	Antithyroglobulin Antibody (TG-Ab) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-TG-CT	Thyroglobulin (TG) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-TSH-CT	Thyroid Stimulating Hormone (TSH) Test Kit (CLIA)	RPS/1227/2025	Self-declaration Others
CI-VB12-CT	Vitamin B12 (VB12) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-VD-CT	25 OH Vitamin D (25-OH VD) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
CI-βHCG-CT	Beta- human Chorionic Gonadotropin(Beta-HCG) Test Kit (CLIA)	RPS/1226/2025	Self-declaration Others
Biochemistry			
DCMGODCI/ DCMGDHCI/ DCGDHCI	Blood Glucose Strip	RPS/1174/2025	Self-declaration Others
DCKETCI	Blood Ketone Strip	RPS/1174/2025	Self-declaration Others
DCTCHCI	Cholesterol Strip	RPS/1174/2025	Self-declaration Others
DCUACI	Uric Acid Strip	RPS/1174/2025	Self-declaration Others
U031-01~14	Urinalysis Reagents Dipstick 1 -14 parameters (Urine)	RPS/1222/2025	Self-declaration Others
U032-CT01~14	Urinalysis Reagent Strips - 01-14 parameters	RPS/1223/2025	Self-declaration Others
WB-ENA-CT711	Anti-Extractable Nuclear Antigen (ENA) Antibody Profile Test Kit (Immunoblotting)	RPS/1227/2025	Self-declaration Others
WB-IFlgE-CT211 ~CT1611	Inhalant-Food Allergen-specific IgE Antibodies Test Kit (Immunoblotting)	RPS/1227/2025	Self-declaration Others