

Certificate of Compliance



We hereby declare that the technical files of all the items in each product group of complied with the requirements of the (98/79/EC) In-Vitro Diagnostic Devices Directive

Certificate No.: CE-7056

Manufacturer

Name : LAB-CARE DIAGNOSTICS (INDIA) PRIVATE LIMITED

Address : C1 TYPE, SHED NO.3225, CHEMICAL ZONE, GIDC SARIGAM,
VALSAD, GUJARAT, 396155, INDIA

Product : DIAGNOSTIC KITS
(MORE DETAILS AS PER THE APPENDIX I-XII)

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to (98/79/EC) In-Vitro Diagnostic Devices Directive

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.org.uk/verify

Date of Initial Registration	03rd September 2025
Date of This Certificate	02nd September 2026
Certificate Expiry	02nd September 2027
Recertification Due	02nd September 2028

(subject to the company maintaining its system to the required standard)



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Appendix-I

Appendix to Certificate no.:- CE-7056

Manufacturer

:- LAB-CARE DIAGNOSTICS (INDIA) PRIVATE LIMITED

Address

:- C1 TYPE, SHED NO.3225, CHEMICAL ZONE, GIDC SARIGAM, VALSAD, GUJARAT, 396155, INDIA



This certificate referred to above covers the following products like:

Products:-

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
52906	Qualitative or Quantitative estimation of Acid Phosphatase	Acid Phosphatase Estimation Kit	ACP	General Product as per Annex II of IVDD 98/79/EC
52921	Qualitative or Quantitative estimation of Adenosine Deaminase	Adenosine Deaminase Estimation Kit	ADA	General Product as per Annex II of IVDD 98/79/EC
59071	Qualitative or Quantitative estimation of Albumin	Albumin Estimation Kit	ALB	General Product as per Annex II of IVDD 98/79/EC
52930	Qualitative or Quantitative estimation of Alkaline Phosphatase	Alkaline phosphatase Estimation Kit	APL	General Product as per Annex II of IVDD 98/79/EC
59073	Qualitative or Quantitative estimation of Amylase	Amylase Estimation Kit	AMYSLR	General Product as per Annex II of IVDD 98/79/EC
45789	Qualitative or Quantitative estimation of Calcium	Calcium (Arsenazo III) Estimation Kit	CARZ	General Product as per Annex II of IVDD 98/79/EC
60037	Qualitative or Quantitative estimation of Chloride	Chloride Estimation Kit	CHLO	General Product as per Annex II of IVDD 98/79/EC
53359	Qualitative or Quantitative estimation of Cholesterol	Cholesterol Estimation Kit	CHOLSLR	General Product as per Annex II of IVDD 98/79/EC
52971	Qualitative or Quantitative estimation of Cholinesterase	Cholinesterase Estimation Kit	CHOLEN	General Product as per Annex II of IVDD 98/79/EC

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Appendix-I

Appendix to Certificate no.:- CE-7056

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:- LAB-CARE DIAGNOSTICS (INDIA) PRIVATE LIMITED

Address

:- C1 TYPE, SHED NO.3225, CHEMICAL ZONE, GIDC SARIGAM, VALSAD, GUJARAT, 396155, INDIA



This certificate referred to above covers the following products like:

Products: -

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
52994	Qualitative or Quantitative estimation of Creatine Kinase - MB	CK-MB Estimation Kit	MBSLR	General Product as per Annex II of IVDD 98/79/EC
53001	Qualitative or Quantitative estimation of Creatine Kinase	CK-Nac Estimation Kit	CKSLR	General Product as per Annex II of IVDD 98/79/EC
53251	Qualitative or Quantitative estimation of Creatinine	Creatinine 2 Liquid Estimation Kit	CRESLR	General Product as per Annex II of IVDD 98/79/EC
52930	Qualitative or Quantitative estimation of Alkaline Phosphatase	Alkaline phosphatase Mono Estimation Kit	APLM	General Product as per Annex II of IVDD 98/79/EC
53229	Qualitative or Quantitative estimation of Total Bilirubin	Bilirubin Total Estimation Kit	TBIL	General Product as per Annex II of IVDD 98/79/EC
53233	Qualitative or Quantitative estimation of Direct Bilirubin	Bilirubin Direct Estimation Kit	DBIL	General Product as per Annex II of IVDD 98/79/EC
53391	Qualitative or Quantitative estimation of HDL- Cholesterol	Direct-HDL Estimation Kit	DHDL	General Product as per Annex II of IVDD 98/79/EC
53395	Qualitative or Quantitative estimation of LDL- Cholesterol	Direct-LDL Estimation Kit	DLDL	General Product as per Annex II of IVDD 98/79/EC
55931	Qualitative or Quantitative estimation of Glucose 6 Phosphate Dehydrogenase	G6PD Estimation Kit	GDPDSLR	General Product as per Annex II of IVDD 98/79/EC

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71-75 Shelton Street, Covent Garden, London, WC2H 9JQ, United Kingdom

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Company No. 11847851



Certificate of Compliance

Appendix-I

Appendix to Certificate no.:- CE-7056

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:- LAB-CARE DIAGNOSTICS (INDIA) PRIVATE LIMITED

Address

:- C1 TYPE, SHED NO.3225, CHEMICAL ZONE, GIDC SARIGAM, VALSAD, GUJARAT, 396155, INDIA



This certificate referred to above covers the following products like:

Products:-

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
53027	Qualitative or Quantitative estimation of gamma-glutamyl transferase (GGT)	Gamma GT Estimation Kit	GGTSLR	General Product as per Annex II of IVDD 98/79/EC
59090	Qualitative or Quantitative estimation of Glycosylated Hemoglobin	Glycosylated Hb Estimation Kit	GHB	General Product as per Annex II of IVDD 98/79/EC
53301	Qualitative or Quantitative estimation of Glucose	Glucose SLR Estimation Kit	GLUSLR	General Product as per Annex II of IVDD 98/79/EC
55872	Qualitative or Quantitative estimation of Hemoglobin	Hemoglobin Estimation Kit	HM	General Product as per Annex II of IVDD 98/79/EC
53391	Qualitative or Quantitative estimation of HDL-Cholesterol	HDL PPT Estimation Kit	HDL	General Product as per Annex II of IVDD 98/79/EC
54758	Qualitative or Quantitative estimation of Iron	Iron Estimation Kit	FE	General Product as per Annex II of IVDD 98/79/EC
53072	Qualitative or Quantitative estimation of Lactate Dehydrogenase	LDH L-P Estimation Kit	LDHSLR	General Product as per Annex II of IVDD 98/79/EC
53108	Qualitative or Quantitative estimation of Lipase	Lipase Estimation Kit	LIPSLR	General Product as per Annex II of IVDD 98/79/EC
46795	Qualitative or Quantitative estimation of Magnesium	Magnesium SLR Estimation Kit	MAG	General Product as per Annex II of IVDD 98/79/EC

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: C1 TYPE, SHED NO.3225, CHEMICAL ZONE, GIDC SARIGAM, VALSAD, GUJARAT, 396155, INDIA



This certificate referred to above covers the following products like:

Products: -

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
59085	Qualitative or Quantitative estimation of Microprotein	Microprotein Estimation Kit	MTP	General Product as per Annex II of IVDD 98/79/EC
59123	Qualitative or Quantitative estimation of Phosphorus	Phosphorus Estimation Kit	PHOS	General Product as per Annex II of IVDD 98/79/EC
63357	Qualitative or Quantitative estimation of Potassium	Potassium Estimation Kit	KM	General Product as per Annex II of IVDD 98/79/EC
52954	Qualitative or Quantitative estimation of Aspartate transaminase	SGOT /AST Estimation Kit	GOTSLR	General Product as per Annex II of IVDD 98/79/EC
52924	Qualitative or Quantitative estimation of Alanine transaminase	SGPT / ALT Estimation Kit	GPTSLR	General Product as per Annex II of IVDD 98/79/EC
52899	Qualitative or Quantitative estimation of Sodium	Sodium Estimation Kit	SODM	General Product as per Annex II of IVDD 98/79/EC
61900	Qualitative or Quantitative estimation of Total Protein	Total Protein Estimation Kit	TP	General Product as per Annex II of IVDD 98/79/EC
53460	Qualitative or Quantitative estimation of Triglyceride	Triglyceride Estimation Kit	TGLSLR	General Product as per Annex II of IVDD 98/79/EC
53587	Qualitative or Quantitative estimation of Urea	Urea UV Estimation Kit	URESRLR	General Product as per Annex II of IVDD 98/79/EC
63333	Qualitative or Quantitative estimation of Urea berthelot	Urea Berthelot Estimation Kit	LURE	General Product as per Annex II of IVDD 98/79/EC

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:- C1 TYPE, SHED NO.3225, CHEMICAL ZONE, GIDC SARIGAM, VALSAD, GUJARAT, 396155, INDIA



This certificate referred to above covers the following products like:

Products: -

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
53583	Qualitative or Quantitative estimation of Uric Acid	Uric Acid Estimation Kit	URISLR	General Product as per Annex II of IVDD 98/79/EC
53251	Qualitative or Quantitative estimation of Creatinine	Creatinine Single Estimation Kit	CRES	General Product as per Annex II of IVDD 98/79/EC
55931	Qualitative or Quantitative estimation of Glucose 6 Phosphate Dehydrogenase	G6PD Quantitative Powder Estimation Kit	G6PDQ	General Product as per Annex II of IVDD 98/79/EC
55931	Qualitative or Quantitative estimation of Glucose 6 Phosphate Dehydrogenase	G6PD Qualitative Screening Kit	G6PDS	General Product as per Annex II of IVDD 98/79/EC
63271	Qualitative or Quantitative estimation of Antistreptolysin O	ASO Latex Slide Agglutination Kit	ASO	General Product as per Annex II of IVDD 98/79/EC
63234	Qualitative or Quantitative estimation of C-Reactive Protein	CRP Latex Slide Agglutination Kit	CRP	General Product as per Annex II of IVDD 98/79/EC
55112	Qualitative or Quantitative estimation of Rheumatoid Factor (RF)	RF Latex Slide Agglutination Kit	RF	General Product as per Annex II of IVDD 98/79/EC
63271	Qualitative or Quantitative estimation of Antistreptolysin O	Quantitative Estimation of ASO (Anti-Streptolysin-O) Turbilateral Kit	TASO	General Product as per Annex II of IVDD 98/79/EC
53705	Qualitative or Quantitative estimation of C-Reactive Protein	Quantitative Estimation of CRP (C-Reactive Protein) Turbilateral Kit	TCRP	General Product as per Annex II of IVDD 98/79/EC
55111	Qualitative or Quantitative estimation of Rheumatoid Factor (RF)	Quantitative Estimation of RF (Rheumatoid Factor) Turbilateral Kit	TRF	General Product as per Annex II of IVDD 98/79/EC
59090	Qualitative or Quantitative estimation of Glycosylated Hemoglobin	Quantitative Estimation of HbA1c Turbilateral Kit	HBAC	General Product as per Annex II of IVDD 98/79/EC

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Appendix-I

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This certificate referred to above covers the following products like:

Products: -

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
53475	Qualitative or Quantitative estimation of Albumin	Quantitative Estimation of Microalbumin Turbilatex Kit	MALB	General Product as per Annex II of IVDD 98/79/EC
51819	Qualitative or Quantitative estimation of VDRL Antigen	RPR (Rapid Plasma Reagin) flocculation Slide Test Kit	RPR	General Product as per Annex II of IVDD 98/79/EC
51819	Qualitative or Quantitative estimation of VDRL Antigen	VDRL RED flocculation Slide Test Kit	VDRL	General Product as per Annex II of IVDD 98/79/EC
51552	Qualitative or Quantitative estimation of Salmonella Typhi / Paratyphi Antibody	WIDAL Slide Test flocculation Kit for qualitative and semi quantitative determination of Salmonella Tyhi / Paratyphi infection	WIS	General Product as per Annex II of IVDD 98/79/EC
51552	Qualitative or Quantitative estimation of Salmonella Typhi / Paratyphi Antibody	WIDAL Tube Test Kit for semi quantitative determination of Salmonella Tyhi / Paratyphi infection	WIT	General Product as per Annex II of IVDD 98/79/EC
62366	Qualitative or Quantitative estimation of Brucella Abortus & Melitensis Antibody	Brucella A & M Kit for qualitative and semi quantitative determination of Brucella Abortus & Brucella Melitensis infection	BAM	General Product as per Annex II of IVDD 98/79/EC
54518	Qualitative or Quantitative estimation of Glucose in Urine	Diachex (Glucose) kit for estimation Glucose in urine	URG	General Product as per Annex II of IVDD 98/79/EC
54514	Qualitative or Quantitative estimation of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, Ph, Protein, Urobilinogen, Nitrite and Leukocyte in Urine	Keto-Diachex (Glucose / Ketone) kit for estimation Glucose and Ketone in urine	URGK	General Product as per Annex II of IVDD 98/79/EC
54514	Qualitative or Quantitative estimation of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, Ph, Protein, Urobilinogen, Nitrite and Leukocyte in Urine	Urichex+ (Glucose / Protein / pH) kit for estimation Glucose, Protein and pH in urine	URGPH	General Product as per Annex II of IVDD 98/79/EC

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Appendix-I

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C1 TYPE, SHED NO.3225, CHEMICAL ZONE, GIDC SARIGAM, VALSAD, GUJARAT, 396155, INDIA



This certificate referred to above covers the following products like:

Products:-

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
54514	Qualitative or Quantitative estimation of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, Ph, Protein, Urobilinogen, Nitrite and Leukocyte in Urine	Keto-Urichex (Glucose / Ketone / Protein) kit for estimation Glucose, Ketone and Protein in urine	URGPK	General Product as per Annex II of IVDD 98/79/EC
54514	Qualitative or Quantitative estimation of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, Ph, Protein, Urobilinogen, Nitrite and Leukocyte in Urine	Combichex (Glucose / Protein / pH / Specific Gravity) kit for estimation Glucose, Protein, pH and Specific Gravity in urine	URSG	General Product as per Annex II of IVDD 98/79/EC
54514	Qualitative or Quantitative estimation of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, Ph, Protein, Urobilinogen, Nitrite and Leukocyte in Urine	Labchex (5 Para) kit for estimation Glucose, Protein, pH and Specific Gravity in urine	URLX	General Product as per Annex II of IVDD 98/79/EC
54514	Qualitative or Quantitative estimation of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, Ph, Protein, Urobilinogen, Nitrite and Leukocyte in Urine	Multichex (10 Para) kit for estimation Glucose, Bilirubin, Ketone, Specific Gravity, Blood, Ph, Protein, Urobilinogen, Nitrite and Leukocyte in urine	URM	General Product as per Annex II of IVDD 98/79/EC
54528	Qualitative or Quantitative estimation of Blood in stool.	Occult Blood Stool Card kits used to	STOCC	General Product as per Annex II of IVDD 98/79/EC
52311	Qualitative or Quantitative estimation of Malaria Plasmodium Falciparum / Vivax in Human Blood	Malaria Pf/Pv Antigen Rapid Card Test	MAGC	General Product as per Annex II of IVDD 98/79/EC
46989	Qualitative or Quantitative estimation of Troponin I	Troponin I Rapid Card Test	TPI	General Product as per Annex II of IVDD 98/79/EC

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Appendix-I

Appendix to Certificate no.:- CE-7056

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This certificate referred to above covers the following products like:

Products:-

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
63726	Qualitative or Quantitative estimation of IgG & IgM Antibodies for Leptospira	Leptospira IgG / IgM Rapid Card Test	LEPC	General Product as per Annex II of IVDD 98/79/EC
51020	Qualitative or Quantitative estimation of Antibodies for Helicobacter Pylori	H.Pylori Antibody Rapid Card Test	HPBC	General Product as per Annex II of IVDD 98/79/EC
30825	Qualitative or Quantitative estimation of Helicobacter Pylori Antigen	H.Pylori Antigen Rapid Card Test	HPGC	General Product as per Annex II of IVDD 98/79/EC
63238	Qualitative or Quantitative estimation of IgG & IgM Antibodies for Dengue	Dengue IgG / IgM Rapid Card Test	DENC	General Product as per Annex II of IVDD 98/79/EC
62928	Qualitative or Quantitative estimation of Dengue Antigen & Antibody	Dengue Duo Rapid Card Test	DENCC	General Product as per Annex II of IVDD 98/79/EC
62946	Qualitative or Quantitative estimation of Dengue Antigen	Dengue NS1 Rapid Card Test	DENS1	General Product as per Annex II of IVDD 98/79/EC
51562	Qualitative or Quantitative estimation of IgG & IgM Antibodies for Salmonella Typhi	S.Typhi IgG / IgM Ab Rapid Card Test	TABC	General Product as per Annex II of IVDD 98/79/EC
51560	Qualitative or Quantitative estimation of Salmonella Typhi & Paratyphi 'A' Antigen	S.Typhi / P.Typhi 'A' Ag Rapid Card Test	TAGC	General Product as per Annex II of IVDD 98/79/EC
64824	Qualitative or Quantitative estimation of IgG Antibody for COVID-19	COVID-19 IgG ELISA Test	CVEG	General Product as per Annex II of IVDD 98/79/EC
64787	Qualitative or Quantitative estimation of COVID-19 Antigen	COVID-19 Ag Card Test	CVGC	General Product as per Annex II of IVDD 98/79/EC

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This certificate referred to above covers the following products like:

Products:-

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
63970	Qualitative or Quantitative estimation of IgG & IgM Antibodies for Chikungunya	Chikungunya IgG / IgM Rapid Card Test	CAGMC	General Product as per Annex II of IVDD 98/79/EC
49119	Qualitative or Quantitative estimation of Influenza A & B	Influenza A + B Rapid Card Test	IFLC	General Product as per Annex II of IVDD 98/79/EC
51801	Qualitative or Quantitative estimation of Antibodies for Syphilis	Syphilis Antibody Rapid Card Test	SYPC	General Product as per Annex II of IVDD 98/79/EC
33819	Qualitative or Quantitative estimation of Human chorionic gonadotropin (hCG)	Pregnancy (hCG) Rapid Card Test	HCGC	General Product as per Annex II of IVDD 98/79/EC
48287	Qualitative or Quantitative estimation of Antibodies for Hepatitis A Virus	HAV Antibody Rapid Card Test	HAVC	General Product as per Annex II of IVDD 98/79/EC
64756	Qualitative or Quantitative estimation of IgG & IgM Antibody for COVID-19	COVID-19 IgG / IgM Lateral Flow Assay Test Kit	COVC	General Product as per Annex II of IVDD 98/79/EC
64747	Qualitative or Quantitative estimation of Nucleic Acid for COVID-19	Novel Coronavirus (2019-nCoV) RT-PCR Kit	RPCR	General Product as per Annex II of IVDD 98/79/EC
62392	Microbiological medium for preservation and transportation of Micro Organisms	VIRAL TRANSPORT MEDIUM	VTM	General Product as per Annex II of IVDD 98/79/EC
54476	Qualitative or Quantitative estimation of 25-hydroxyvitamin D	Vitamin D Turbilateral Test Kit	TVD	General Product as per Annex II of IVDD 98/79/EC
63713	Qualitative or Quantitative estimation of D Dimer	D-Dimer Turbilateral Test Kit	TDR	General Product as per Annex II of IVDD 98/79/EC

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This certificate referred to above covers the following products like:

Products:-

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
53718	Qualitative or Quantitative estimation of Ferritin	Ferritin Turbilatex Test Kit	TFN	General Product as per Annex II of IVDD 98/79/EC
65316	SARS-CoV-2 neutralizing antibody IVD, kit, enzyme immunoassay (EIA)	COVID-19 Neutralizing Antibody ELISA Kit	CENB	General Product as per Annex II of IVDD 98/79/EC
60774	Carbon dioxide (CO2) IVD, reagent	Bicarbonate Estimation Kit	BIC	General Product as per Annex II of IVDD 98/79/EC
53751	Homocysteine IVD, reagent	Homocysteine Estimation Kit	HCY	General Product as per Annex II of IVDD 98/79/EC
53251	Qualitative or Quantitative estimation of Creatinine	Creatinine Enzymatic Estimation Kit	CREZ	General Product as per Annex II of IVDD 98/79/EC
53301	Qualitative or Quantitative estimation of Glucose	Glucose (Hexokinase) Estimation Kit	GHK	General Product as per Annex II of IVDD 98/79/EC
47869	Multiple-type clinical chemistry analyte profile IVD, control	Chemistry Control Normal & Abnormal	CCC	General Product as per Annex II of IVDD 98/79/EC
47868	Multiple-type clinical chemistry analyte profile IVD, calibrator	Chemistry Calibrator	CC	General Product as per Annex II of IVDD 98/79/EC
55872	Qualitative or Quantitative estimation of Hemoglobin	Sickle Cell Assay Kit (Solubility Assay for Detection of Hemoglobin S)	HBSS	General Product as per Annex II of IVDD 98/79/EC
54528	Qualitative or Quantitative estimation of Blood in stool.	iFOB Rapid Test Kit	FOBC	General Product as per Annex II of IVDD 98/79/EC

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This certificate referred to above covers the following products like:

Products:-

GMDN CODE	GMDN TERMS	PRODUCT NAME	MODEL	CLASSIFICATION
52311	Multiple Plasmodium species antigen IVD, kit, rapid ICT, clinical	Malaria Pf/Pan Antigen Rapid Test Kit	MGNC	General Product as per Annex II of IVDD 98/79/EC
54255	Luteinizing hormone (LH) IVD, kit, rapid ICT, clinical	Luteinizing hormone (LH) Rapid Test Kit	LHC	General Product as per Annex II of IVDD 98/79/EC
65991	Allergen-specific immunoglobulin E (IgE) antibody IVD, kit, rapid ICT, clinical	IgE Rapid Test Kit	IGEC	General Product as per Annex II of IVDD 98/79/EC

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