

## DECLARATION OF CONFORMITY

1) **Manufacturer:**

**Ameritech Diagnostic Reagent (Jiaxing) Co., Ltd.**

Address: K4-2 ScienceTechnologyGarden, Economic Development Zone, 314500 Tongxiang,  
Zhejiang,P.R. China.

2) **European authorized representative:CEpartner4U BV,**

Address:**ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS.www.cepartner4u.com)

3) **Product(s)**(name, type or model/batch number, etc.):

<p><b>- dBest Rapid tests</b> see appendix</p>
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4) The product(s) described above is in conformity with:

<u>Title</u>	<u>Document No.</u>
<i>In vitro</i> Diagnostic Medical Devices Directive	98/79/EC

5) **Additional information**(conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure for CE marking: Medical Device Directive

Low Risk Devices – Annex III

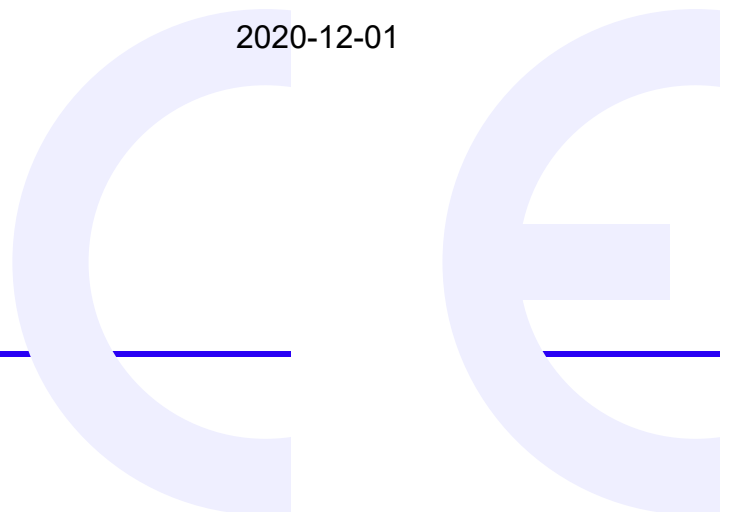
Self Test Devices - Annex III. Section 6, Notified Body and NB-no: TÜV SÜD, #0123

List B Devices- Annex II, Notified Body and NB-no: TÜV SÜD, #0123

Tongxiang, ChinaLijian Cheng (Manager)

2020-12-01

By: Lijian Cheng



## Appendix

Date: 2020-7-24

List of devices:

Group 1a: RAPID Test

Device name	Risk Class	Type / model	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>					
Tumor Marker					
CEA Serum	Low Risk	R20-110	1203013100	2015.3.31	
CEA Serum	Low Risk	R20-112	1203013100	2015.3.31	
CEA Serum/Whole Blood	Low Risk	R20-116	1203013100	2015.3.31	
Semi-quantitative CEA Serum	Low Risk	SQ20-112	1203013100	2015.3.31	
Semi-quantitative CEA Serum/Whole Blood	Low Risk	SQ20-116	1203013100	2015.3.31	
AFP Serum	Low Risk	*R00-110	1203900100	2015.3.31	
AFP Serum	Low Risk	*R00-112	1203900100	2015.3.31	
AFP Serum/Whole Blood	Low Risk	*R00-116	1203900100	2015.3.31	
Semi-quantitative AFP Serum	Low Risk	*SQ00-112	1203900100	2015.3.31	
Semi-quantitative AFP Serum/Whole Blood	Low Risk	*SQ00-116	1203900100	2015.3.31	
Bladder Cancer Urine Test	Low Risk	*R01-110	1203010100	2015.3.31	
Bladder Cancer Urine Test	Low Risk	*R01-112	1203010100	2015.3.31	
OB HB-HP Combo	Low Risk	R42-112	1203900400	2015.3.31	
OB complex Combo	Low Risk	R43-112	1203900400	2015.3.31	
Fertility					
hCG Pregnancy Urine, Sensitivity 20 mIU	Low Risk	R04-110	1270050200	2015.3.31	
hCG Pregnancy Urine, Sensitivity 20 mIU	Low Risk	R04-100	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 20 mIU	Low Risk	R04-112	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 20 mIU	Low Risk	R04-104	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 20 mIU	Low Risk	R04-N-104	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-100	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-110	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-112	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-104	1270050200	2015.3.31	
hCG Panel	Low Risk	R04-140	1270050200	2015.3.31	
2000 mIU/ml hCG Urine	Low Risk	R05-110	1270050200	2015.3.31	
2000 mIU/ml hCG Urine	Low Risk	R05-112	1270050200	2015.3.31	
hCG Pregnancy Urine/Serum	Low Risk	R06-100	1270050200	2015.3.31	
hCG Pregnancy Urine/Serum	Low Risk	R06-110	1270050200	2015.3.31	
hCG Pregnancy Urine/Serum	Low Risk	R06-112	1270050200	2015.3.31	
FSH Urine	Low Risk	R17-112	1270050100	2015.3.31	
FSH Urine	Low Risk	R17-114	1270050100	2015.3.31	
hCG Pregnancy Urine, Sensitivity 5 mIU	Low Risk	R04-510	1270050200	2015.3.31	
hCG Pregnancy Urine, Sensitivity 5 mIU	Low Risk	R04-512	1270050200	2015.3.31	
hCG Pregnancy Urine, Sensitivity 5 mIU	Low Risk	R04-514	1270050200	2015.3.31	
Drug of Abuse					
Cocaine	Low Risk	R24-110	1270090600	2015.3.31	

Device name	Risk Class	Type / model	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>					
Cocaine	Low Risk	R24-112	1270090600	2015.3.31	
BAR	Low Risk	R25-110	1270090300	2015.3.31	
BAR	Low Risk	R25-112	1270090300	2015.3.31	
Methamphetamine	Low Risk	R26-110	1209010200	2015.3.31	
Methamphetamine	Low Risk	R26-112	1209010200	2015.3.31	
BZD	Low Risk	R27-110	1270090400	2015.3.31	
BZD	Low Risk	R27-112	1270090400	2015.3.31	
Morphine/Heroin/Opiate	Low Risk	R28-110	1270090800	2015.3.31	
Morphine/Heroin/Opiate	Low Risk	R28-112	1270090800	2015.3.31	
MTD	Low Risk	R29-110	1270090700	2015.3.31	
MTD	Low Risk	R29-112	1270090700	2015.3.31	
THC	Low Risk	R30-110	1270090500	2015.3.31	
THC	Low Risk	R30-112	1270090500	2015.3.31	
PCP	Low Risk	R31-110	1270090900	2015.3.31	
PCP	Low Risk	R31-112	1270090900	2015.3.31	
Amphetamine	Low Risk	R32-110	1270090100	2015.3.31	
Amphetamine	Low Risk	R32-112	1270090100	2015.3.31	
TCA	Low Risk	R33-110	1209021500	2015.3.31	
TCA	Low Risk	R33-112	1209021500	2015.3.31	
Cotinine	Low Risk	R152-110	1209010800	2015.3.31	
Cotinine	Low Risk	R152-112	1209010800	2015.3.31	
MDMA	Low Risk	R41-110	1209019000	2015.3.31	
MDMA	Low Risk	R41-112	1209019000	2015.3.31	
Oxycodone	Low Risk	R51-110	1209019000	2015.3.31	
Oxycodone	Low Risk	R51-112	1209019000	2015.3.31	
Buprenorphine	Low Risk	R53-110	1209019000	2015.3.31	
Buprenorphine	Low Risk	R53-112	1209019000	2015.3.31	
Ketamine	Low Risk	R52-110	1209019000	2015.3.31	
Ketamine	Low Risk	R52-112	1209019000	2015.3.31	
EDDP	Low Risk	R61-110	1209019000	2015.3.31	
EDDP	Low Risk	R61-112	1209019000	2015.3.31	
Fentanyl	Low Risk	R74-110	1209019000	2015.3.31	
Fentanyl	Low Risk	R74-112	1209019000	2015.3.31	
MultiDrugs-2 Test panel	Low Risk	R153-200	1209019000	2015.3.31	
MultiDrugs-3 Test panel	Low Risk	R153-300	1209019000	2015.3.31	
MultiDrugs-3 Test panel A	Low Risk	R153-300A	1209019000	2015.3.31	
MultiDrugs-3 Test panel B	Low Risk	R153-300B	1209019000	2015.3.31	
MultiDrugs-3 Test panel C	Low Risk	R153-300C	1209019000	2015.3.31	
MultiDrugs-3 Test panel D	Low Risk	R153-300D	1209019000	2015.3.31	
MultiDrugs-3 Test panel E	Low Risk	R153-300E	1209019000	2015.3.31	
MultiDrugs-3 Test panel F	Low Risk	R153-300F	1209019000	2015.3.31	
MultiDrugs-3 Test panel G	Low Risk	R153-300G	1209019000	2015.3.31	
MultiDrugs-3 Test panel H	Low Risk	R153-300H	1209019000	2015.3.31	
MultiDrugs-3 Test panel I	Low Risk	R153-300I	1209019000	2015.3.31	
MultiDrugs-3 Test panel J	Low Risk	R153-300J	1209019000	2015.3.31	

Device name	Risk Class	Type / model	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>					
MultiDrugs-3 Test panel K	Low Risk	R153-300K	1209019000	2015.3.31	
MultiDrugs-3 Test panel L	Low Risk	R153-300L	1209019000	2015.3.31	
MultiDrugs-3 Test panel M	Low Risk	R153-300M	1209019000	2015.3.31	
MultiDrugs-3 Test panel N	Low Risk	R153-300N	1209019000	2015.3.31	
MultiDrugs-4 Test panel	Low Risk	R153-400	1209019000	2015.3.31	
MultiDrugs-5 Test panel	Low Risk	R153-500	1209019000	2015.3.31	
MultiDrugs-5 Test panel A	Low Risk	R153-500A	1209019000	2015.3.31	
MultiDrugs-5 Test panel B	Low Risk	R153-500B	1209019000	2015.3.31	
MultiDrugs-5 Test panel C	Low Risk	R153-500C	1209019000	2015.3.31	
MultiDrugs-5 Test panel D	Low Risk	R153-500D	1209019000	2015.3.31	
MultiDrugs-5 Test panel E	Low Risk	R153-500E	1209019000	2015.3.31	
MultiDrugs-5 Test panel F	Low Risk	R153-500F	1209019000	2015.3.31	
MultiDrugs-5 Test panel G	Low Risk	R153-500G	1209019000	2015.3.31	
MultiDrugs-5 Test panel H	Low Risk	R153-500H	1209019000	2015.3.31	
MultiDrugs-6 Test panel	Low Risk	R153-600	1209019000	2015.3.31	
MultiDrugs-6 Test panel A	Low Risk	R153-600A	1209019000	2015.3.31	
MultiDrugs-6 Test panel B	Low Risk	R153-600B	1209019000	2015.3.31	
MultiDrugs-6 Test panel C	Low Risk	R153-600C	1209019000	2015.3.31	
MultiDrugs-7 Test panel	Low Risk	R153-700	1209019000	2015.3.31	
MultiDrugs-8 Test panel	Low Risk	R153-800	1209019000	2015.3.31	
MultiDrugs-9 Test panel	Low Risk	R153-900	1209019000	2015.3.31	
MultiDrugs-10Test panel	Low Risk	R153-1000	1209019000	2015.3.31	
MultiDrugs-10Test panel A	Low Risk	R153-1000A	1209019000	2015.3.31	
MultiDrugs-10Test panel B	Low Risk	R153-1000B	1209019000	2015.3.31	
MultiDrugs-10Test panel C	Low Risk	R153-1000C	1209019000	2015.3.31	
MultiDrugs-10Test panel D	Low Risk	R153-1000D	1209019000	2015.3.31	
MultiDrugs-10Test panel E	Low Risk	R153-1000E	1209019000	2015.3.31	
MultiDrugs-11Test panel	Low Risk	R153-1100	1209019000	2015.3.31	
MultiDrugs-12Test panel	Low Risk	R153-1200	1209019000	2015.3.31	
<b>Infectious Diseases</b>					
M.Tuberculosis serum	Low Risk	R09-110	1501070300	2015.3.31	
M.Tuberculosis serum	Low Risk	R09-112	1501070300	2015.3.31	
M.Tuberculosis Whole Blood/Serum	Low Risk	R09-116	1501070300	2015.3.31	
M.TuberculosisComboSerum	Low Risk	R09-C-110	1501070300	2015.3.31	
M.TuberculosisComboWhole Blood/Serum	Low Risk	R09-C-116	1501070300	2015.3.31	
Malaria Whole Blood (pf)	Low Risk	R10-110	1570019000	2015.3.31	
Malaria Whole Blood (pf)	Low Risk	R10-116	1570019000	2015.3.31	
Malaria Whole Blood (pv)	Low Risk	R11-110	1570019000	2015.3.31	
Malaria Whole Blood (pv)	Low Risk	R11-116	1570019000	2015.3.31	
Malaria Whole Blood Combo	Low Risk	R13-110	1570019000	2015.3.31	
Malaria Whole Blood Combo	Low Risk	R13-116	1570019000	2015.3.31	
H.pylori Serum	Low Risk	R18-110	1570010200	2015.3.31	
H.pylori Serum	Low Risk	R18-112	1570010200	2015.3.31	
H.pylori Serum/ Whole Blood	Low Risk	R18-116	1570010200	2015.3.31	
H.pyloriSalive-Urease	Low Risk	R102-110	1570010200	2015.3.31	

Device name	Risk Class	Type / model	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>					
H.pyloriSalive-Urease	Low Risk	R102-112	1570010200	2015.3.31	
Strep A	Low Risk	R34-110	1570010300	2015.3.31	
Strep A	Low Risk	R34-112	1570010300	2015.3.31	
Strep B	Low Risk	R66-110	1570010300	2015.3.31	
Strep B	Low Risk	R66-112	1570010300	2015.3.31	
Syphilis Serum	Low Risk	R92-110	1570010500	2015.3.31	
Syphilis Serum	Low Risk	R92-112	1570010500	2015.3.31	
Syphilis,Serum/Whole Blood	Low Risk	R92-116	1570010500	2015.3.31	
Mononucleosis(IgM) Serum	Low Risk	R70-110	1504041100	2015.3.31	
Mononucleosis(IgM) Serum	Low Risk	R70-112	1504041100	2015.3.31	
Mononucleosis(IgM)Whole Blood/Serum	Low Risk	R70-116	1504041100	2015.3.31	
Dengue IgG Serum	Low Risk	*R84-110	1504801100	2015.3.31	
Dengue IgG Serum	Low Risk	*R84-112	1504801100	2015.3.31	
Dengue IgM Serum	Low Risk	*R85-110	1504801100	2015.3.31	
Dengue IgM Serum	Low Risk	*R85-112	1504801100	2015.3.31	
Dengue NS1	Low Risk	R88-112	1504801100	2015.3.31	
Dengue IgG/IgM	Low Risk	R98-112	1504801100	2015.3.31	
Influenza	Low Risk	R89-110	1504800400	2015.3.31	
Influenza	Low Risk	R89-112	1504800400	2015.3.31	
Influenza A/B panel	Low Risk	R90-112	1504800400	2015.3.31	
Covid-19-Ag	Low Risk	R190-112	1504809000	2020.9-20	
Covid-19-Panel test	Low Risk	R191-112	1504809000	2020-9-20	
SCREEN FLU	Low Risk	R90-112	1504800400	2015.3.31	
E.Coli	Low Risk	R104-110	1501154000	2015.3.31	
E.Coli	Low Risk	R104-112	1501154000	2015.3.31	
LISTERIA	Low Risk	R105-110	1501130300	2015.3.31	
LISTERIA	Low Risk	R105-112	1501130300	2015.3.31	
SALMONELLA	Low Risk	R106-110	1501100300	2015.3.31	
SALMONELLA	Low Risk	R106-112	1501100300	2015.3.31	
TB Combo Test	Low Risk	R09-C-112	1501070300	2015.3.31	
TB Combo Whole Blood Test	Low Risk	R09-C-116	1501070300	2015.3.31	
H. Pylori Ag Stool Test	Low Risk	R108-110	1570010200	2015.3.31	
H. Pylori Ag Stool Test	Low Risk	R108-112	1570010200	2015.3.31	
Rotavirus	Low Risk	R93-112	1504800600	2015.3.31	
Adenovirus	Low Risk	R94-112	1504800100	2015.3.31	
Trichomonus	Low Risk	R97-112	1504809000	2015.3.31	
Rota/Adeno	Low Risk	R95-112	1504800100	2015.3.31	
Legionella Pneumophila	Low Risk	R19-110	1504800100	2015.3.31	
Legionella Pneumophila	Low Risk	R19-112	1504800100	2015.3.31	
H. Pylori Latex Antigen Stool	Low Risk	R109-112	1570010200	2015.3.31	
Cardiac Marker				2015.3.31	
Troponin I Whole Blood/Serum	Low Risk	R22-112	1270130300	2015.3.31	
Myoglobin Whole Blood/Serum	Low Risk	R23-112	1270130200	2015.3.31	
CRP Whole Blood/Serum	Low Risk	SQ182-116	1270110100	2015.3.31	

Device name	Risk Class	Type / model	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>					
Troponin I,CK-MB, Myoglobin Whole Blood/Serum	Low Risk	R180-116	1213019000	2015.3.31	
Dimer-D Whole blood/Serum	Low Risk	R118-116	1213019000	2015.3.31	
h-FABP	Low Risk	R183-116	1213019000	2015.3.31	
GPBB (Glycogen phosphorylase BB)	Low Risk	R189-112	1213010400	2020.7.24	
Allergy				2015.3.31	
IgE Serum	Low Risk	R14-110	1202010200	2015.3.31	
IgE Serum	Low Risk	R14-112	1202010200	2015.3.31	
IgE Serum/ Whole Blood	Low Risk	R14-116	1202010200	2015.3.31	
Urinalysis Multistrips				2015.3.31	
Glucose	Low Risk	U02-001	1102011300	2015.3.31	
Glucose/Ketone	Low Risk	U02-002	1170020200	2015.3.31	
Glucose/Ketone/PH	Low Risk	U02-003	1170020200	2015.3.31	
Glucose/Ketone/PH/Blood	Low Risk	U02-004	1170020200	2015.3.31	
Glucose/Ketone/PH/Blood/Protein	Low Risk	U02-005	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili	Low Risk	U02-006	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil	Low Risk	U02-007	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/Nit	Low Risk	U02-008	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/ S.Gravity/ Nit	Low Risk	U02-009	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/ S.Gravity/ Nit/Leukocytes	Low Risk	U02-010	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/ S.Gravity/ Nit/Leukocytes/Ascorbic	Low Risk	U02-011	1170020200	2015.3.31	
Vaginal pH	Low Risk	V03-01	1570019000	2015.3.31	
Vaginal pH	Low Risk	V03-02	1570019000	2015.3.31	
Creatinine	Low Risk	UC-02	1170020200	2015.3.31	
Miscellaneous				2015.3.31	
Alcohol Strip	Low Risk	R107-110	1209020700	2015.3.31	
UTI Stick (Urinary Track Infection)	Low Risk	UT-01	1570019000	2015.3.31	
Femlab	Low Risk	V02-512	1570019000	2015.3.31	
Occult Blood	Low Risk	R40-110	1203900400	2015.3.31	
Occult Blood	Low Risk	R40-112	1203900400	2015.3.31	
Occult Blood (Sample collection tube)	Low Risk	R40S-110	1203900400	2015.3.31	
Occult Blood (Sample collection tube)	Low Risk	R40S-112	1203900400	2015.3.31	
The new generation OB test	Low Risk	R402-112	1203900400	2019.7.25	
OB hb-transferrin-combo	Low Risk	R44-112	1203900400	2015.3.31	
Albumin Urine	Low Risk	R50-110	1102010100	2015.3.31	
Albumin Urine	Low Risk	R50-112	1102010100	2015.3.31	
Albumin Urine-Simple	Low Risk	R55-110	1102010100	2015.3.31	
Albumin Urine-Simple	Low Risk	R55-112	1102010100	2015.3.31	
Semi-quantitative Albumin Urine	Low Risk	SQ50-110	1102010100	2015.3.31	
Semi-quantitative Albumin Urine	Low Risk	SQ50-112	1102010100	2015.3.31	
Rheumatoid Factor(RF) Serum	Low Risk	R15-110	1211011000	2015.3.31	
Rheumatoid Factor(RF) Serum	Low Risk	R15-112	1211011000	2015.3.31	

Device name	Risk Class	Type / model	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>					
RF Serum/Whole Blood	Low Risk	R15-116	1211011000	2015.3.31	
Neonatal TSH Whole Blood	Low Risk	R76-116	1204010300	2015.3.31	
TSH Serum	Low Risk	R72-110	1204011100	2015.3.31	
TSH Serum	Low Risk	R72-112	1204011100	2015.3.31	
TSH Serum/Whole Blood	Low Risk	R72-116	1204011100	2015.3.31	
Feritin Serum	Low Risk	R100-110	1207010200	2015.3.31	
Feritin Serum	Low Risk	R100-112	1207010200	2015.3.31	
Feritin Whole Blood/Serum	Low Risk	R100-116	1207010200	2015.3.31	
Feritin Whole Blood/Serum	Low Risk	SQ100-116	1207010200	2015.3.31	
High-LevelFeritin Whole Blood/Serum	Low Risk	R101-116	1207010200	2015.3.31	
Calprotectin	Low Risk	R88-112	1213019000	2015.3.31	
Fecal Occult Blood	Low Risk	B00-610	1203900400	2015.3.31	
Fecal Occult Blood With Specimen Sticks And Envelopes	Low Risk	B00-630	1203900400	2015.3.31	
Candida Strip	Low Risk	R36-110	1506010200	2015.3.31	
Candida Cassette	Low Risk	R36-112	1506010200	2015.3.31	
CRP semi-quantitative Whole Blood/Serum	Low Risk	SQ184-116	1270110100	2015.3.31	
CRP semi-quantitative Whole Blood/Serum	Low Risk	SQ185-116	1270110100	2015.3.31	
Adiponectin whole blood	Low Risk	SQ190-116	1270110100	2015.3.31	
C. Difficile Toxiin A/B 2-panel	Low Risk	R200-112	1504800100	2015.3.31	
Cholerae stool test	Low Risk	R305-110	1504800100	2015.3.31	
Cholerae stool test	Low Risk	R305-112	1504800100	2015.3.31	
Gonorrhoea	Low Risk	R300-110	1504800100	2015.3.31	
Gonorrhoea	Low Risk	R300-112	1504800100	2015.3.31	
RSV	Low Risk	R310-112	1504800100	2015.3.31	
Femlab-EU	Low Risk	V02-512-EU	1570019000	2015.3.31	
hsCRPsemi-quantitative Whole Blood/Serum	Low Risk	SQ182-112	1270110100	2015.3.31	
Bone Marker	Low Risk	B02-112	1203010100	2015.3.31	
Vaginitis panel	Low Risk	V04	1506010200	2015.3.31	
Creatinine Albumin	Low Risk	CA-10	1170020200	2015.3.31	
Latex H. Pylori Antigen	Low Risk	R109-112	1570010200	2015.3.31	

**GROUP 1b: RAPID Test / Self test**

Device name	Risk Class	P/N	EDMS-code	CE-certificate	First date of CE-marking	Final date of CE-marking
<b><u>Rapid test / Self-testing</u></b>						
Chlamydia Trachomatis Test	List B	R16-110 R16-112	15.01.01.01	V11079870002	2016-4-28	
Early Pregnancy (hCG) Test	Self-Test	R110-114 R04-114 R04-120	12.70.05.02	V11079870002	2019-1-22	
dBest H. Pylori Saliva (HPS) Test Kit	Self-Test	R102-112 R102-114 Exacto-858795	15.70.01.02	V11079870002	2018-8-14	