

## 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.):**

**- dBest Rapid tests**  
see appendix

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 IV excluding (4, 6), Notified Body and NB-no: TÜV SÜD, #0123

List B Devices- Annex IV excluding (4, 6), Notified Body and NB-no: TÜV SÜD, #0123

6) ISO 13485 Certificate: Notified Body: TÜV SÜD, Valid until: 2024-07-07

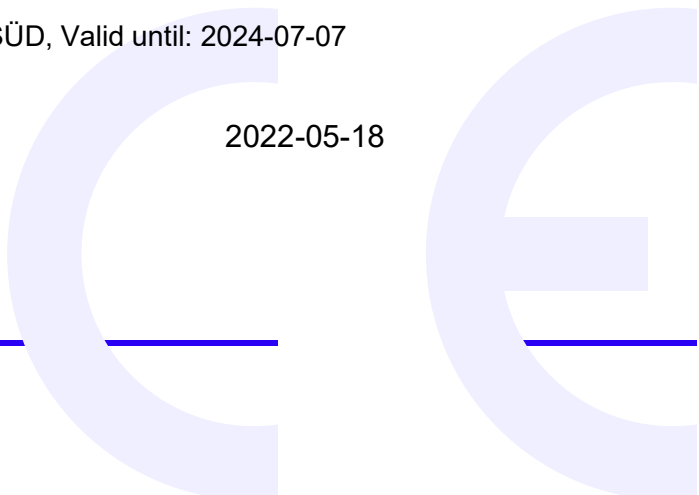
Tongxiang, ChinaLijian Cheng (Manager)

2022-05-18

By: \_\_\_\_\_

*Lijian Cheng*

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## Appendix

Date: 2022-5-18

List of devices:  
Group 1a: RAPID Test

Device name	Risk Class	Type / model	EMDN code	UDI-DI code	EUDAMED DI code	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>								
Tumor Marker								
CEA Serum	Low Risk	R20-110	W0102160299	06941571820106	B-06941571820106	1203013100	2015.3.31	
CEA Serum	Low Risk	R20-112	W0102160299	06941571820205	B-06941571820205	1203013100	2015.3.31	
CEA Serum/Whole Blood	Low Risk	R20-116	W0102160299	06941571820304	B-06941571820304	1203013100	2015.3.31	
Semi-quantitative CEA Serum	Low Risk	SQ20-112	W0102160299	06941571820403	B-06941571820403	1203013100	2015.3.31	
Semi-quantitative CEA Serum/Whole Blood	Low Risk	SQ20-116	W0102160299	06941571820502	B-06941571820502	1203013100	2015.3.31	
AFP Serum	Low Risk	*R00-110	W0102160299	06941571800207	B-06941571800207	1203900100	2015.3.31	
AFP Serum	Low Risk	*R00-112	W0102160299	06941571800306	B-06941571800306	1203900100	2015.3.31	
AFP Serum/Whole Blood	Low Risk	*R00-116	W0102160299	06941571800405	B-06941571800405	1203900100	2015.3.31	
Semi-quantitative AFP Serum	Low Risk	*SQ00-112	W0102160299	06941571800504	B-06941571800504	1203900100	2015.3.31	
Semi-quantitative AFP Serum/Whole Blood	Low Risk	*SQ00-116	W0102160299	06941571800603	B-06941571800603	1203900100	2015.3.31	
Bladder Cancer Marker Test	Low Risk	R01S-112	W0102160201	06941571801006	B-06941571801006			
Bladder Cancer Urine Test	Low Risk	*R01-110	W0102160201	06941571801105	B-06941571801105	1203010100	2015.3.31	
Bladder Cancer Urine Test	Low Risk	*R01-112	W0102160201	06941571801204	B-06941571801204	1203010100	2015.3.31	
OB HB-HP Combo	Low Risk	R42-112	W0102160299	06941571842009	B-06941571842009	1203900400	2015.3.31	
OB complex Combo	Low Risk	R43-112	W0102160299	06941571843006	B-06941571843006	1203900400	2015.3.31	
Fertility								
hCG Pregnancy Urine, Sensitivity 20 mIU	Low Risk	R04-110	W0102160302	06941571804007	B-06941571804007	1270050200	2015.3.31	
hCG Pregnancy Urine, Sensitivity 20 mIU	Low Risk	R04-100	W0102160302	06941571804106	B-06941571804106	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 20 mIU	Low Risk	R04-112	W0102160302	06941571804205	B-06941571804205	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 20 mIU	Low Risk	R04-104	W0102160302	06941571804304	B-06941571804304	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 20 mIU	Low Risk	R04-N-104	W0102160302	06941571804403	B-06941571804403	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-100	W0102160302	06941571811005	B-06941571811005	1270050200	2015.3.31	

Device name	Risk Class	Type / model	EMDN code	UDI-DI code	EUDAMED DI code	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>								
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-110	W0102160302	06941571811012	B-06941571811012	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-112	W0102160302	06941571811029	B-06941571811029	1270050200	2015.3.31	
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-104	W0102160302	06941571811036	B-06941571811036	1270050200	2015.3.31	
hCG Panel	Low Risk	R04-140	W0102160302	06941571804502	B-06941571804502	1270050200	2015.3.31	
2000 mIU/ml hCG Urine	Low Risk	R05-110	W0102160302	06941571805004	B-06941571805004	1270050200	2015.3.31	
2000 mIU/ml hCG Urine	Low Risk	R05-112	W0102160302	06941571805103	B-06941571805103	1270050200	2015.3.31	
hCG Pregnancy Urine/Serum	Low Risk	R06-100	W0102160302	06941571806001	B-06941571806001	1270050200	2015.3.31	
hCG Pregnancy Urine/Serum	Low Risk	R06-110	W0102160302	06941571806100	B-06941571806100	1270050200	2015.3.31	
hCG Pregnancy Urine/Serum	Low Risk	R06-112	W0102160302	06941571806209	B-06941571806209	1270050200	2015.3.31	
FSH Urine	Low Risk	R17-112	W0102160301	06941571817007	B-06941571817007	1270050100	2015.3.31	
FSH Urine	Low Risk	R17-114	W0102160301	06941571817106	B-06941571817106	1270050100	2015.3.31	
hCG Pregnancy Urine, Sensitivity 5 mIU	Low Risk	R04-510	W0102160302	06941571804601	B-06941571804601	1270050200	2015.3.31	
hCG Pregnancy Urine, Sensitivity 5 mIU	Low Risk	R04-512	W0102160302	06941571804700	B-06941571804700	1270050200	2015.3.31	
hCG Pregnancy Urine, Sensitivity 5 mIU	Low Risk	R04-514	W0102160302	06941571804809	B-06941571804809	1270050200	2015.3.31	
<b>Drug of Abuse</b>								
Cocaine	Low Risk	R24-110	W0102160506	06941571824005	B-06941571824005	1270090600	2015.3.31	
Cocaine	Low Risk	R24-112	W0102160506	06941571824104	B-06941571824104	1270090600	2015.3.31	
BAR	Low Risk	R25-110	W0102160503	06941571825002	B-06941571825002	1270090300	2015.3.31	
BAR	Low Risk	R25-112	W0102160503	06941571825101	B-06941571825101	1270090300	2015.3.31	
Methamphetamine	Low Risk	R26-110	W0102160502	06941571826009	B-06941571826009	1209010200	2015.3.31	
Methamphetamine	Low Risk	R26-112	W0102160502	06941571826108	B-06941571826108	1209010200	2015.3.31	
BZD	Low Risk	R27-110	W0102160504	06941571827006	B-06941571827006	1270090400	2015.3.31	
BZD	Low Risk	R27-112	W0102160504	06941571827105	B-06941571827105	1270090400	2015.3.31	
Morphine/Heroin/Opiate	Low Risk	R28-110	W0102160508	06941571828003	B-06941571828003	1270090800	2015.3.31	
Morphine/Heroin/Opiate	Low Risk	R28-112	W0102160508	06941571828102	B-06941571828102	1270090800	2015.3.31	
MTD	Low Risk	R29-110	W0102160507	06941571829000	B-06941571829000	1270090700	2015.3.31	
MTD	Low Risk	R29-112	W0102160507	06941571829109	B-06941571829109	1270090700	2015.3.31	
THC	Low Risk	R30-110	W0102160505	06941571830006	B-06941571830006	1270090500	2015.3.31	
THC	Low Risk	R30-112	W0102160505	06941571830105	B-06941571830105	1270090500	2015.3.31	
PCP	Low Risk	R31-110	W0102160509	06941571831003	B-06941571831003	1270090900	2015.3.31	
PCP	Low Risk	R31-112	W0102160509	06941571831102	B-06941571831102	1270090900	2015.3.31	

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<b>Rapid test</b>								
Amphetamine	Low Risk	R32-110	W0102160501	06941571832000	B-06941571832000	1270090100	2015.3.31	
Amphetamine	Low Risk	R32-112	W0102160501	06941571832109	B-06941571832109	1270090100	2015.3.31	
TCA	Low Risk	R33-110	W0102160510	06941571833007	B-06941571833007	1209021500	2015.3.31	
TCA	Low Risk	R33-112	W0102160510	06941571833106	B-06941571833106	1209021500	2015.3.31	
Cotinine	Low Risk	R152-110	W0102160599	06941571815201	B-06941571815201	1209010800	2015.3.31	
Cotinine	Low Risk	R152-112	W0102160599	06941571815218	B-06941571815218	1209010800	2015.3.31	
MDMA	Low Risk	R41-110	W0102160502	06941571841002	B-06941571841002	1209019000	2015.3.31	
MDMA	Low Risk	R41-112	W0102160502	06941571841101	B-06941571841101	1209019000	2015.3.31	
Oxycodone	Low Risk	R51-110	W0102160599	06941571851001	B-06941571851001	1209019000	2015.3.31	
Oxycodone	Low Risk	R51-112	W0102160599	06941571851100	B-06941571851100	1209019000	2015.3.31	
Buprenorphine	Low Risk	R53-110	W0102160599	06941571853005	B-06941571853005	1209019000	2015.3.31	
Buprenorphine	Low Risk	R53-112	W0102160599	06941571853104	B-06941571853104	1209019000	2015.3.31	
Ketamine	Low Risk	R52-110	W0102160599	06941571852008	B-06941571852008	1209019000	2015.3.31	
Ketamine	Low Risk	R52-112	W0102160599	06941571852107	B-06941571852107	1209019000	2015.3.31	
EDDP	Low Risk	R61-110	W0102160507	06941571861000	B-06941571861000	1209019000	2015.3.31	
EDDP	Low Risk	R61-112	W0102160507	06941571861109	B-06941571861109	1209019000	2015.3.31	
Fentanyl	Low Risk	R74-110	W0102160599	06941571874000	B-06941571874000	1209019000	2015.3.31	
Fentanyl	Low Risk	R74-112	W0102160599	06941571874109	B-06941571874109	1209019000	2015.3.31	
MultiDrugs-2 Test panel	Low Risk	R153-200	W0102160511	06941571815300	B-06941571815300	1209019000	2015.3.31	
MultiDrugs-3 Test panel	Low Risk	R153-300	W0102160511	06941571815317	B-06941571815317	1209019000	2015.3.31	
MultiDrugs-3 Test panel A	Low Risk	R153-300A	W0102160511	06941571815324	B-06941571815324	1209019000	2015.3.31	
MultiDrugs-3 Test panel B	Low Risk	R153-300B	W0102160511	06941571815331	B-06941571815331	1209019000	2015.3.31	
MultiDrugs-3 Test panel C	Low Risk	R153-300C	W0102160511	06941571815348	B-06941571815348	1209019000	2015.3.31	
MultiDrugs-3 Test panel D	Low Risk	R153-300D	W0102160511	06941571815355	B-06941571815355	1209019000	2015.3.31	
MultiDrugs-3 Test panel E	Low Risk	R153-300E	W0102160511	06941571815362	B-06941571815362	1209019000	2015.3.31	
MultiDrugs-3 Test panel F	Low Risk	R153-300F	W0102160511	06941571815379	B-06941571815379	1209019000	2015.3.31	
MultiDrugs-3 Test panel G	Low Risk	R153-300G	W0102160511	06941571815386	B-06941571815386	1209019000	2015.3.31	
MultiDrugs-3 Test panel H	Low Risk	R153-300H	W0102160511	06941571815393	B-06941571815393	1209019000	2015.3.31	
MultiDrugs-3 Test panel I	Low Risk	R153-300I	W0102160511	06941571815409	B-06941571815409	1209019000	2015.3.31	
MultiDrugs-3 Test panel J	Low Risk	R153-300J	W0102160511	06941571815416	B-06941571815416	1209019000	2015.3.31	
MultiDrugs-3 Test panel K	Low Risk	R153-300K	W0102160511	06941571815423	B-06941571815423	1209019000	2015.3.31	

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<b>Rapid test</b>								
MultiDrugs-3 Test panel L	Low Risk	R153-300L	W0102160511	06941571815430	B-06941571815430	1209019000	2015.3.31	
MultiDrugs-3 Test panel M	Low Risk	R153-300M	W0102160511	06941571815447	B-06941571815447	1209019000	2015.3.31	
MultiDrugs-3 Test panel N	Low Risk	R153-300N	W0102160511	06941571815454	B-06941571815454	1209019000	2015.3.31	
MultiDrugs-4 Test panel	Low Risk	R153-400	W0102160511	06941571815461	B-06941571815461	1209019000	2015.3.31	
MultiDrugs-5 Test panel	Low Risk	R153-500	W0102160511	06941571815478	B-06941571815478	1209019000	2015.3.31	
MultiDrugs-5 Test panel A	Low Risk	R153-500A	W0102160511	06941571815485	B-06941571815485	1209019000	2015.3.31	
MultiDrugs-5 Test panel B	Low Risk	R153-500B	W0102160511	06941571815492	B-06941571815492	1209019000	2015.3.31	
MultiDrugs-5 Test panel C	Low Risk	R153-500C	W0102160511	06941571815508	B-06941571815508	1209019000	2015.3.31	
MultiDrugs-5 Test panel D	Low Risk	R153-500D	W0102160511	06941571815515	B-06941571815515	1209019000	2015.3.31	
MultiDrugs-5 Test panel E	Low Risk	R153-500E	W0102160511	06941571815522	B-06941571815522	1209019000	2015.3.31	
MultiDrugs-5 Test panel F	Low Risk	R153-500F	W0102160511	06941571815539	B-06941571815539	1209019000	2015.3.31	
MultiDrugs-5 Test panel G	Low Risk	R153-500G	W0102160511	06941571815546	B-06941571815546	1209019000	2015.3.31	
MultiDrugs-5 Test panel H	Low Risk	R153-500H	W0102160511	06941571815553	B-06941571815553	1209019000	2015.3.31	
MultiDrugs-6 Test panel	Low Risk	R153-600	W0102160511	06941571815560	B-06941571815560	1209019000	2015.3.31	
MultiDrugs-6 Test panel A	Low Risk	R153-600A	W0102160511	06941571815577	B-06941571815577	1209019000	2015.3.31	
MultiDrugs-6 Test panel B	Low Risk	R153-600B	W0102160511	06941571815584	B-06941571815584	1209019000	2015.3.31	
MultiDrugs-6 Test panel C	Low Risk	R153-600C	W0102160511	06941571815591	B-06941571815591	1209019000	2015.3.31	
MultiDrugs-7 Test panel	Low Risk	R153-700	W0102160511	06941571815607	B-06941571815607	1209019000	2015.3.31	
MultiDrugs-8 Test panel	Low Risk	R153-800	W0102160511	06941571815614	B-06941571815614	1209019000	2015.3.31	
MultiDrugs-9 Test panel	Low Risk	R153-900	W0102160511	06941571815621	B-06941571815621	1209019000	2015.3.31	
MultiDrugs-10 Test panel	Low Risk	R153-1000	W0102160511	06941571815638	B-06941571815638	1209019000	2015.3.31	
MultiDrugs-10 Test panel A	Low Risk	R153-1000A	W0102160511	06941571815645	B-06941571815645	1209019000	2015.3.31	
MultiDrugs-10 Test panel B	Low Risk	R153-1000B	W0102160511	06941571815652	B-06941571815652	1209019000	2015.3.31	
MultiDrugs-10 Test panel C	Low Risk	R153-1000C	W0102160511	06941571815669	B-06941571815669	1209019000	2015.3.31	
MultiDrugs-10 Test panel D	Low Risk	R153-1000D	W0102160511	06941571815676	B-06941571815676	1209019000	2015.3.31	
MultiDrugs-10 Test panel E	Low Risk	R153-1000E	W0102160511	06941571815683	B-06941571815683	1209019000	2015.3.31	
MultiDrugs-11 Test panel	Low Risk	R153-1100	W0102160511	06941571815690	B-06941571815690	1209019000	2015.3.31	
MultiDrugs-12 Test panel	Low Risk	R153-1200	W0102160511	06941571815706	B-06941571815706	1209019000	2015.3.31	
MultiDrugs-12 Test panel A	Low Risk	R153-1200A	W0102160511	06941571815713	B-06941571815713	1209019000	2015.3.31	
<b>Infectious Diseases</b>								
M.Tuberculosis serum	Low Risk	R09-110	W0105090199	06941571809002	B-06941571809002	1501070300	2015.3.31	

Device name	Risk Class	Type / model	EMDN code	UDI-DI code	EUDAMED DI code	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>								
M.Tuberculosis serum	Low Risk	R09-112	W0105090199	06941571809019	B-06941571809019	1501070300	2015.3.31	
M.Tuberculosis Whole Blood/Serum	Low Risk	R09-116	W0105090199	06941571809026	B-06941571809026	1501070300	2015.3.31	
M.Tuberculosis Combo serum	Low Risk	R09-C-110	W0105090199	06941571809033	B-06941571809033	1501070300	2015.3.31	
M.Tuberculosis Combo Whole Blood/Serum	Low Risk	R09-C-116	W0105090199	06941571809040	B-06941571809040	1501070300	2015.3.31	
Malaria Whole Blood (pf)	Low Risk	R10-110	W0105090401	06941571810008	B-06941571810008	1570019000	2015.3.31	
Malaria Whole Blood (pf)	Low Risk	R10-116	W0105090401	06941571810015	B-06941571810015	1570019000	2015.3.31	
Malaria Whole Blood (pv)	Low Risk	R11-110	W0105090401	06941571811104	B-06941571811104	1570019000	2015.3.31	
Malaria Whole Blood (pv)	Low Risk	R11-116	W0105090401	06941571811111	B-06941571811111	1570019000	2015.3.31	
Malaria Whole Blood Combo	Low Risk	R13-110	W0105090401	06941571813009	B-06941571813009	1570019000	2015.3.31	
Malaria Whole Blood Combo	Low Risk	R13-116	W0105090401	06941571813016	B-06941571813016	1570019000	2015.3.31	
H.pylori Serum	Low Risk	R18-110	W0105090102	06941571818004	B-06941571818004	1570010200	2015.3.31	
H.pylori Serum	Low Risk	R18-112	W0105090102	06941571818011	B-06941571818011	1570010200	2015.3.31	
H.pylori Serum/ Whole Blood	Low Risk	R18-116	W0105090102	06941571818028	B-06941571818028	1570010200	2015.3.31	
H.pylori Salive-Urease	Low Risk	R102-110	W0105090102	06941571810206	B-06941571810206	1570010200	2015.3.31	
H.pylori Salive-Urease	Low Risk	R102-112	W0105090102	06941571810213	B-06941571810213	1570010200	2015.3.31	
Strep A	Low Risk	R34-110	W0105090103	06941571834004	B-06941571834004	1570010300	2015.3.31	
Strep A	Low Risk	R34-112	W0105090103	06941571834011	B-06941571834011	1570010300	2015.3.31	
Strep B	Low Risk	R66-110	W0105090104	06941571866005	B-06941571866005	1570010300	2015.3.31	
Strep B	Low Risk	R66-112	W0105090104	06941571866012	B-06941571866012	1570010300	2015.3.31	
Syphilis Serum	Low Risk	R92-110	W0105090105	06941571892004	B-06941571892004	1570010500	2015.3.31	
Syphilis Serum	Low Risk	R92-112	W0105090105	06941571892011	B-06941571892011	1570010500	2015.3.31	
Syphilis Serum/Whole Blood	Low Risk	R92-116	W0105090105	06941571892028	B-06941571892028	1570010500	2015.3.31	
Mononucleosis(IgM) Serum	Low Risk	R70-110	W0105099003	06941571870002	B-06941571870002	1504041100	2015.3.31	
Mononucleosis(IgM) Serum	Low Risk	R70-112	W0105099003	06941571870019	B-06941571870019	1504041100	2015.3.31	
Mononucleosis(IgM) Whole Blood/Serum	Low Risk	R70-116	W0105099003	06941571870026	B-06941571870026	1504041100	2015.3.31	
Dengue IgG Serum	Low Risk	R84-110	W0105099007	06941571884009	B-06941571884009	1504801100	2015.3.31	
Dengue IgG Serum	Low Risk	R84-112	W0105099007	06941571884016	B-06941571884016	1504801100	2015.3.31	
Dengue IgM Serum	Low Risk	R85-110	W0105099007	06941571885006	B-06941571885006	1504801100	2015.3.31	
Dengue IgM Serum	Low Risk	R85-112	W0105099007	06941571885013	B-06941571885013	1504801100	2015.3.31	
Dengue NS1	Low Risk	R330-112	W0105099007	06941571833205	B-06941571833205	1504801100	2015.3.31	

Device name	Risk Class	Type / model	EMDN code	UDI-DI code	EUDAMED DI code	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>								
Dengue IgG/IgM	Low Risk	R98-112	W0105099007	06941571898006	B-06941571898006	1504801100	2015.3.31	
Influenza	Low Risk	R89-110	W0105099004	06941571889004	B-06941571889004	1504800400	2015.3.31	
Influenza	Low Risk	R89-112	W0105099004	06941571889011	B-06941571889011	1504800400	2015.3.31	
Influenza A/B panel	Low Risk	R90-112	W0105099004	06941571890000	B-06941571890000	1504800400	2015.3.31	
Covid-19-Ag Rapid test	Low Risk	R190-112	W0105099099	06941571819001	B-06941571819001	1504809000	2020.9.20	
Covid-19-Ag Panel Rapid test	Low Risk	R191-112	W0105099099	06941571819100	B-06941571819100	1504809000	2020.9.20	
SCREEN FLU	Low Risk	R90-112	W0105099004	06941571890109	B-06941571890109	1504800400	2015.3.31	
E.Coli	Low Risk	R104-110	W0105090199	06941571810404	B-06941571810404	1501154000	2015.3.31	
E.Coli	Low Risk	R104-112	W0105090199	06941571810411	B-06941571810411	1501154000	2015.3.31	
LISTERIA	Low Risk	R105-110	W0105090199	06941571810503	B-06941571810503	1501130300	2015.3.31	
LISTERIA	Low Risk	R105-112	W0105090199	06941571810510	B-06941571810510	1501130300	2015.3.31	
SALMONELLA	Low Risk	R106-110	W0105090199	06941571810602	B-06941571810602	1501100300	2015.3.31	
SALMONELLA	Low Risk	R106-112	W0105090199	06941571810619	B-06941571810619	1501100300	2015.3.31	
TB Combo Test	Low Risk	R09-C-112	W0105090199	06941571809057	B-06941571809057	1501070300	2015.3.31	
H. Pylori Ag Stool Test	Low Risk	R108-110	W0105090102	06941571810800	B-06941571810800	1570010200	2015.3.31	
H. Pylori Ag Stool Test	Low Risk	R108-112	W0105090102	06941571810817	B-06941571810817	1570010200	2015.3.31	
Rotavirus	Low Risk	R93-112	W0105099099	06941571893001	B-06941571893001	1504800600	2015.3.31	
Adenovirus	Low Risk	R94-112	W0105099099	06941571894008	B-06941571894008	1504800100	2015.3.31	
Trichomonus	Low Risk	R97-112	W0105090199	06941571897009	B-06941571897009	1504809000	2015.3.31	
Rota/Adeno	Low Risk	R95-112	W0105099099	06941571895005	B-06941571895005	1504800100	2015.3.31	
Legionella Pneumophila	Low Risk	R19-110	W0105090108	06941571819209	B-06941571819209	1504800100	2015.3.31	
Legionella Pneumophila	Low Risk	R19-112	W0105090108	06941571819216	B-06941571819216	1504800100	2015.3.31	
H. Pylori Latex Antigen Stool	Low Risk	R109-112	W0105090102	06941571810909	B-06941571810909	1570010200	2015.3.31	
Cardiac Marker							2015.3.31	
Troponin I Whole Blood/Serum	Low Risk	R22-112	W0102160703	06941571822001	B-06941571822001	1270130300	2015.3.31	
Myoglobin Whole Blood/Serum	Low Risk	R23-112	W0102160702	06941571823008	B-06941571823008	1270130200	2015.3.31	
CRP Whole Blood/Serum	Low Risk	SQ182-116	W0102160601	06941571818202	B-06941571818202	1270110100	2015.3.31	
Troponin I,CK-MB, Myoglobin Whole Blood/Serum	Low Risk	R180-116	W0102160706	06941571818097	B-06941571818097	1270130900	2015.3.31	
Dimer-D Whole blood/Serum	Low Risk	R118-116	W0103020803	06941571811807	B-06941571811807	1302050300	2015.3.31	
h-FABP	Low Risk	R183-116	W0102160705	06941571818301	B-06941571818301	1213010300	2015.3.31	

Device name	Risk Class	Type / model	EMDN code	UDI-DI code	EUDAMED DI code	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>								
GPBB (Glycogen phosphorylase BB)	Low Risk	R189-112	W0102160799	06941571818905	B-06941571818905	1213010400	2020.7.24	
Allergy							2015.3.31	
IgE Serum	Low Risk	R14-110	W01020201	06941571814006	B-06941571814006	1202010200	2015.3.31	
IgE Serum	Low Risk	R14-112	W01020201	06941571814013	B-06941571814013	1202010200	2015.3.31	
IgE Serum/ Whole Blood	Low Risk	R14-116	W01020201	06941571814020	B-06941571814020	1202010200	2015.3.31	
Urinalysis Multistrips							2015.3.31	
Glucose	Low Risk	U02-001	W0101060201	06941571802003	B-06941571802003	1102011300	2015.3.31	
Glucose/Ketone	Low Risk	U02-002	W0101060204	06941571802010	B-06941571802010	1170020200	2015.3.31	
Glucose/Ketone/PH	Low Risk	U02-003	W0101060204	06941571802027	B-06941571802027	1170020200	2015.3.31	
Glucose/Ketone/PH/Blood	Low Risk	U02-004	W0101060204	06941571802034	B-06941571802034	1170020200	2015.3.31	
Glucose/Ketone/PH/Blood/Protein	Low Risk	U02-005	W0101060204	06941571802041	B-06941571802041	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili	Low Risk	U02-006	W0101060204	06941571802058	B-06941571802058	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil	Low Risk	U02-007	W0101060204	06941571802065	B-06941571802065	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/Nit	Low Risk	U02-008	W0101060204	06941571802072	B-06941571802072	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/ S.Gravity/ Nit	Low Risk	U02-009	W0101060204	06941571802089	B-06941571802089	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/ S.Gravity/ Nit/Leukocytes	Low Risk	U02-010	W0101060204	06941571802096	B-06941571802096	1170020200	2015.3.31	
Glu/Ket/PH/Blood/Pro/Bili/Urobil/ S.Gravity/ Nit/Leukocytes/Ascorbic	Low Risk	U02-011	W0101060204	06941571802102	B-06941571802102	1170020200	2015.3.31	
Vaginal pH	Low Risk	V03-01	W01010699	06941571803000	B-06941571803000	1570019000	2015.3.31	
Vaginal pH	Low Risk	V03-02	W01010699	06941571803017	B-06941571803017	1570019000	2015.3.31	
Creatinine	Low Risk	UC-02	W0101060201	06941571803024	B-06941571803024	1170020200	2015.3.31	
Miscellaneous							2015.3.31	
Alcohol Strip	Low Risk	R107-110	W01010699	06941571810701	B-06941571810701	1209020700	2015.3.31	
UTI Stick (Urinary Track Infection)	Low Risk	UT-01	W0101060204	06941571803031	B-06941571803031	1570019000	2015.3.31	
Femlab	Low Risk	V02-512	W01010699	06941571802508	B-06941571802508	1570019000	2015.3.31	
Occult Blood	Low Risk	R40-110	W0103010601	06941571840104	B-06941571840104	1203900400	2015.3.31	
Occult Blood	Low Risk	R40-112	W0103010601	06941571840203	B-06941571840203	1203900400	2015.3.31	
Occult Blood (Sample collection tube)	Low Risk	R40S-110	W0103010601	06941571840111	B-06941571840111	1203900400	2015.3.31	
Occult Blood (Sample collection tube)	Low Risk	R40S-112	W0103010601	06941571840210	B-06941571840210	1203900400	2015.3.31	



Device name	Risk Class	Type / model	EMDN code	UDI-DI code	EUDAMED DI code	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>								
The new generation OB test	Low Risk	R402-112	W0103010601	06941571840227	B-06941571840227	1203900400	2019.7.25	
OB hb-transferrin-combo	Low Risk	R44-112	W0103010601	06941571844003	B-06941571844003	1203900400	2015.3.31	
Albumin Urine	Low Risk	R50-110	W0102160101	06941571850004	B-06941571850004	1102010100	2015.3.31	
Albumin Urine	Low Risk	R50-112	W0102160101	06941571850011	B-06941571850011	1102010100	2015.3.31	
Albumin Urine-Simple	Low Risk	R55-110	W0102160101	06941571855009	B-06941571855009	1102010100	2015.3.31	
Albumin Urine-Simple	Low Risk	R55-112	W0102160101	06941571855016	B-06941571855016	1102010100	2015.3.31	
Semi-quantitative Albumin Urine	Low Risk	SQ50-110	W0102160101	06941571850103	B-06941571850103	1102010100	2015.3.31	
Semi-quantitative Albumin Urine	Low Risk	SQ50-112	W0102160101	06941571850110	B-06941571850110	1102010100	2015.3.31	
Rheumatoid Factor (RF) Serum	Low Risk	R15-110	W0102160699	06941571815003	B-06941571815003	1211011000	2015.3.31	
Rheumatoid Factor (RF) Serum	Low Risk	R15-112	W0102160699	06941571815010	B-06941571815010	1211011000	2015.3.31	
RF Serum/Whole Blood	Low Risk	R15-116	W0102160699	06941571815027	B-06941571815027	1211011000	2015.3.31	
Neonatal TSH Whole Blood	Low Risk	R76-116	W0102160903	06941571876004	B-06941571876004	1204010300	2015.3.31	
TSH Serum	Low Risk	R72-110	W0102160903	06941571872006	B-06941571872006	1204011100	2015.3.31	
TSH Serum	Low Risk	R72-112	W0102160903	06941571872013	B-06941571872013	1204011100	2015.3.31	
TSH Serum/Whole Blood	Low Risk	R72-116	W0102160903	06941571872020	B-06941571872020	1204011100	2015.3.31	
Feritin Serum	Low Risk	R100-110	W01021699	06941571810107	B-06941571810107	1207010200	2015.3.31	
Feritin Serum	Low Risk	R100-112	W01021699	06941571810114	B-06941571810114	1207010200	2015.3.31	
Feritin Whole Blood/Serum	Low Risk	R100-116	W01021699	06941571810121	B-06941571810121	1207010200	2015.3.31	
Feritin Whole Blood/Serum	Low Risk	SQ100-116	W01021699	06941571810138	B-06941571810138	1207010200	2015.3.31	
High-Level Feritin Whole Blood/Serum	Low Risk	R101-116	W01021699	06941571810145	B-06941571810145	1207010200	2015.3.31	
Calprotectin	Low Risk	R88-112	W01021699	06941571888007	B-06941571888007	1213019000	2015.3.31	
Fecal Occult Blood	Low Risk	B00-610	W0101060301	06941571800610	B-06941571800610	1203900400	2015.3.31	
Fecal Occult Blood With Specimen Sticks And Envelopes	Low Risk	B00-630	W0101060301	06941571800634	B-06941571800634	1203900400	2015.3.31	
Candida Strip	Low Risk	R36-110	W0105090199	06941571836008	B-06941571836008	1506010200	2015.3.31	
Candida Cassette	Low Risk	R36-112	W0105090199	06941571836015	B-06941571836015	1506010200	2015.3.31	
CRP semi-quantitative Whole Blood/Serum	Low Risk	SQ184-116	W0102160601	06941571818400	B-06941571818400	1270110100	2015.3.31	
CRP semi-quantitative Whole Blood/Serum	Low Risk	SQ185-116	W0102160601	06941571818509	B-06941571818509	1270110100	2015.3.31	
Adiponectin whole blood	Low Risk	SQ190-116	W01021699	06941571819056	B-06941571819056	1270110100	2015.3.31	

Device name	Risk Class	Type / model	EMDN code	UDI-DI code	EUDAMED DI code	EDMS-code	First date of CE-marking	Final date of CE-marking
<b>Rapid test</b>								
C. Difficile Toxin A/B 2-panel	Low Risk	R200-112	W0105090106	06941571820007	B-06941571820007	1504800100	2015-3-31	
Cholerae stool test	Low Risk	R305-110	W0105090199	06941571830501	B-06941571830501	1504800100	2015-3-31	
Cholerae stool test	Low Risk	R305-112	W0105090199	06941571830518	B-06941571830518	1504800100	2015-3-31	
Gonorrhea	Low Risk	R300-110	W0105090199	06941571830051	B-06941571830051	1504800100	2015-3-31	
Gonorrhea	Low Risk	R300-112	W0105090199	06941571830068	B-06941571830068	1504800100	2015-3-31	
RSV	Low Risk	R310-112	W0105099002	06941571831058	B-06941571831058	1504800100	2015-3-31	
Femlab-EU	Low Risk	V02-512-EU	W01010699	06941571802515	B-06941571802515	1570019000	2015-3-31	
hsCRP semi-quantitative Whole Blood/Serum	Low Risk	SQ182-112	W0102160601	06941571818257	B-06941571818257	1270110100	2015-3-31	
Bone Marker	Low Risk	B02-112	W0102160199	06941571802607	B-06941571802607	1203010100	2015-3-31	
Vaginitis panel	Low Risk	V04	W0105090199	06941571804908	B-06941571804908	1506010200	2015-3-31	
Creatinine Albumin	Low Risk	CA-10	W0101060204	06941571803048	B-06941571803048	1170020200	2015-3-31	

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

Device name	Risk Class	P/N	EMDN code	UDI-DI code	EUDAMED DI code	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	W0105090101	06941571816017 06941571816024	B-06941571816017 B-06941571816024	15.01.01.01	V11079870002	2016-4-28	
Early Pregnancy (hCG) Test	Self-Test	R110-114 R04-114 R04-120	W0102160302	06941571800139 06941571800146 06941571800153	B-06941571800139 B-06941571800146 B-06941571800153	12.70.05.02	V11079870002	2019-1-22	
dBest H. Pylori Saliva (HPS) Test Kit	Self-Test	R102-112 R102-114 Exacto-858795	W0105090102	06941571802324 06941571802317 06941571802331	B-06941571802324 B-06941571802317 B-06941571802331	15.70.01.02	V11079870002	2018-8-14	
hCG Panel Test	Self-Test	R04-140	W0102160302	06941571804557	B-06941571804557	12.70.05.02	V11079870002		