DECLARATION OF CONFORMITY

1) **Manufacturer**:

Ameritech Diagnostic Reagent (Jiaxing) Co., Ltd.

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

2) **European authorized representative**: **AR Experts BV,**

Address: **BOEINGAVENUE 209, 1119 PD SCHIPHOL-RIJK, THE NETHERLANDS**;

(on product labels printed as:

AR Experts BV, BOEINGAVENUE 209, 1119 PD SCHIPHOL-RIJK, THE NETHERLANDS. www.ar-experts.eu)

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:

Title	Document No.
In vitro 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 except point 6

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.

Tongxiang, China Lijian Cheng (Manager) 2026-1-20

By: _____

Appendix

Date: 2022-5-20

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
Rapid test								
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	

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
Rapid test								
hCG Pregnancy Urine Sensitivity 10 mIU	Low Risk	R110-100	W0102160302	06941571811005	B-06941571811005	1270050200	2015.3.31	
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	
Drug of Abuse								
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	

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
Rapid test								
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	
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	
Fentany	Low Risk	R74-110	W0102160599	06941571874000	B-06941571874000	1209019000	2015.3.31	
Fentany	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	

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
Rapid test								
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	
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-10Test panel	Low Risk	R153-1000	W0102160511	06941571815638	B-06941571815638	1209019000	2015.3.31	
MultiDrugs-10Test panel A	Low Risk	R153-1000A	W0102160511	06941571815645	B-06941571815645	1209019000	2015.3.31	
MultiDrugs-10Test panel B	Low Risk	R153-1000B	W0102160511	06941571815652	B-06941571815652	1209019000	2015.3.31	
MultiDrugs-10Test panel C	Low Risk	R153-1000C	W0102160511	06941571815669	B-06941571815669	1209019000	2015.3.31	
MultiDrugs-10Test panel D	Low Risk	R153-1000D	W0102160511	06941571815676	B-06941571815676	1209019000	2015.3.31	
MultiDrugs-10Test panel E	Low Risk	R153-1000E	W0102160511	06941571815683	B-06941571815683	1209019000	2015.3.31	
MultiDrugs-11Test panel	Low Risk	R153-1100	W0102160511	06941571815690	B-06941571815690	1209019000	2015.3.31	
MultiDrugs-12Test panel	Low Risk	R153-1200	W0102160511	06941571815706	B-06941571815706	1209019000	2015.3.31	
MultiDrugs-12Test panel A	Low Risk	R153-1200A	W0102160511	06941571815713	B-06941571815713	1209019000	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
Rapid test								
Infectious Diseases								
M.Tuberculosis serum	Low Risk	R09-110	W0105090199	06941571809002	B-06941571809002	1501070300	2015.3.31	
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.TuberculosisComboserum	Low Risk	R09-C-110	W0105090199	06941571809033	B-06941571809033	1501070300	2015.3.31	
M.TuberculosisComboWhole 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.pyloriSalive-Urease	Low Risk	R102-110	W0105090102	06941571810206	B-06941571810206	1570010200	2015.3.31	
H.pyloriSalive-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	
SyphilisSerum/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
Rapid test								
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	
GPBB (Glycogen phosphorylase BB)	Low Risk	R189-112	W0102160799	06941571818905	B-06941571818905	1213010400	2020.7.24	

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
Rapid test								
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	
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	

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
Rapid test								
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-LevelFeritin 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	
C. Difficile Toxiin 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	

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
Rapid test								
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	
hsCRPsemi-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	

Manufacturer's Declaration

In relation to Regulation (EU) 2024/1860amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices,in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC(IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body*and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate)*and/or*
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	Ameritech Diagnostic Reagent (Jiaxing)Co., Ltd
Manufacturer address and contact details	K4-2 Science Technology Garden Economic Development Zone, Tongxiang, Zhejiang China 314500
Single Registration Number (SRN)(if available)	CN-MF-000020607

Authorised Representative name(if applicable)	AR Experts BV
Authorised Representative address and contact details	Boeingavenue 209 1119 PD, Schiphol-Rijk The Netherlands
Single Registration Number (SRN)(if available)	NL-AR-000023989

Notified body name (if applicable)	☐See attached schedule ☐ Not applicable TUV Sud
Notified body number (if applicable)	☐See attached schedule ☐ Not applicable 0123
Directive Certificate number(s) to which this confirmation is made (if applicable)	☐See attached schedule X Not applicable

Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	X See attached schedule ☐ Not applicable
End date of extended validity/transition period	X See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)**listed in the attached schedule the conditions for the legal extension oftransitional periodsas required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)**listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**
  In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

  Choose one applicable statement:

  XFormal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodgedor will be lodgedby us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

  ☐26 May 2025 for class D devices

  X 26 May 2026 for class C devices

  X 27 May 2027 for class B and class A (sterile) devices

  X Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDRfor the device(s) listed in the attached schedule or its/their substitutes no later than:

  ☐26 September 2025 for class D devices

  X 26 September 2026 for class C devices

  X 27 September 2027 for class B and class A (sterile) devices

  ☐We do not intend to lodge an application for conformityfor the device as indicated on the attached schedule.

- **Directive Certificate(s)**as listed above or in the attached schedule

- Directive Certificate(s) covering the device(s)listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 andhas/have not been withdrawnafterwards.

  Choose applicable statements:

  ☐Original expiry date*before 9 July 2024*:

  ☐Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or

  ☐Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR(may be provided upon request), or

  ☐Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, to carry out the applicable conformity assessment procedure(may be provided upon request)

  Choose one of the following statements only if a derogation per Article 54(1) or a requirement per Article 92(1) has been granted by a Competent Authority:

  ☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodgedor will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

  ☐We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

  ☐ Original expiry date*after9 July 2024*:

  Choose one applicable statement:

  - ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodgedor will be lodgedby us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will bein place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.
  - ☐ We do not intend to lodge an application for conformity assessment by 26 May 2025for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.

  ☐ assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  ☐ QMS in accordance with Article 10(8)IVDR will be put in place by no later than 26 May 2025.
  X QMS in accordance with Article 10(8)IVDR is in place.
  ☐ Notified body has issued the attached certificate for the IVDR-compliant QMS.

- **Device(s) listed in the attached schedule(apart from the device indicated to be withdrawn)**
  - The device(s) continue(s) to comply with the IVDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Ameritech Diagnostic Reagent (Jiaxing) Co., Ltd

K4-2 Science Technology Garden

Economic Development Zone

Tongxiang, Zhejiang China 314500

By: 

Lijan Chen (Manager)
clj@ameritek.org

2026-1-8

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**End date of extended validity/transition period**	**Substitute Device(s)** (if applicable)	**Directive Certificate number to which this declarationis issued** (if applicable)	**Original expiry date as indicated on the Directive Certificateprior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
Class B Rapid test	**2027-5-27**					
Class C Rapid Test	**2026-5-26**					

AMERITECH DIAGNOSTIC REAGENT LTD. JIAXING THE PEOPLE'S REPUBLIC OF CHINA

[1]for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above

Appendix for Gima

		CARDIAC test
C	R180-116	Combo 3 Par.(CKMB, Mioglobina,Troponina) box 20pz+man.ENG/ITA/FRA/SPA
C	SQ182-116	Test proteina C reattiva - CRP conf. 20pz
		Vaious test
B	R90-112	INFLUENZA A/B-box 30pz, con 3 inner bags da 10pz
		Gynecology test
B	R04-114	REGULAR MIDSTREAM (x TECNICO - DESA PHARMA) conf 24pz
B	V03-01	TEST pH VAGINALE - 10pz -
B	V02-512	TEST RAPIDO VAGINITE

中国 浙江省 桐乡市 经济开发区 科技园 K4－2 号
K4-2 Science Technology Garden, Economic Development Zone, Tongxiang, Zhejiang, P.R.China
电话：86-573-88111055 电传：86-573-88112156 网址: www.ameritek.com.cn