Abbott

Digitally signed by Ceaicovschi Tudor
Date: 2026.01.02 09:58:14 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANA

EU Declaration of Conformity

Basic UDI-DI: 03874DAL0002FQ
Basic UDI-DI Name: Alinity c Processing Module
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
03R67-01	Alinity c Processing Module	56676	W0201010108

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, Texas 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott, GmbH Max-Planck-Ring 2 65205 Wiesbaden
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Canon Medical Systems Corporation 1385 Shimoishigami, Otawara-Shi Tochigi 324-8550, Japan
Conformity Assessment Procedure	**Annex II and III**

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name:	Kevin Richardson	Full Name:	Amanda Peoples
Function:	Director, Instrument Quality	Function:	Regulatory Affairs Project Manager
Signature:	Kevin Richardson	Signature:	Amanda Peoples
Date of Approval:	11-APRIL-2025	Date of Approval:	11-April-2025
Signed for, and on behalf of:	Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038 USA		
Date Issued:	11-April-2025	Place Issued:	Irving, Texas
Supersedes:	12 September 2024	Effective (Date or Lot Number):	11-April-2025

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories
1915 Hurd Drive
Irving
Texas
75038
USA

Facility ID Number: F005921

Holds Certificate No: **MDSAP 762409**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-12-18 Effective Date: 2024-12-09 Expiry Date: 2027-11-01

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 762409**

Registered Scope:

Design, development, manufacture, and distribution of in vitro diagnostic analyzers for immunoassay and clinical chemistry systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.
Design, development, and manufacture of In Vitro Diagnostic products including instruments, reagents, and accessories for Hematology.

Original Registration Date: 2019-12-18 Effective Date: 2024-12-09 Expiry Date: 2027-11-01

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories
1915 Hurd Drive
Irving
Texas
75038
USA

Holds Certificate Number: MD 762422

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture, distribution and refurbishment of in vitro diagnostic analyzers, reagents, and accessories for immunoassay, clinical chemistry, and hematology systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-06-13
Latest Revision Date: 2024-12-12

Effective Date: 2024-12-12
Expiry Date: 2027-11-01

...making excellence a habit.™

Alinity

Alinity
ci-series

ALINITY | Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

Alinity ci-series System Specifications

CHOOSE TRANSFORMATION™

Achieve measurably better healthcare performance
ABBOTTDIAGNOSTICS.com/ALINITY

Abbott

Alinity

FEATURE	ALINITY c	ALINITY i	ALINITY ci
Dimension (H x W x D)	134 x 119 x 117 cm/1.39 m^2	134 x 119 x 117 cm/1.39 m^2	134 x 199 x 117 cm/2.33 m^2
Methods	Photometric, Potentiometric	Chemiluminescence	Photometric, Potentiometric, Chemiluminescence
Maximum Throughput	Up to 1350 TPH	Up to 200 TPH	Up to 1550 TPH
Throughput/m^2	Up to 971 TPH/m^2	Up to 144 TPH/m^2	Up to 665 TPH/m^2
Scalability	Up to 4 modules controlled by one System Control Module (SCM)		
Continuous Access of Reagents, Calibrators, Controls and Consumables	Yes		
Flexible Stat Options	Prioritize single rack as needed or configure multiple fixed positions		
Sample Types*	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood	Serum, plasma, whole blood, urine	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood
Sample Capacity	150	150	300
Sample Bar Code Types	Code 128, Standard Code 39, Interleaved 2 of 5, Codabar		
Sample Result Storage	200,000		
Dead Volume	50 µL (sample cup)		
Sample Volume*	1.5–35 µL	2–200 µL	Alinity c: 1.5–35 µL Alinity i: 2–200 µL
Sample Probe Carryover	≤0.1 parts per million†		
Reagent Capacity	Up to 70 refrigerated reagent cartridges onboard plus patented ISE (Na+, K+, and Cl-)	Up to 47 refrigerated reagent cartridges onboard	Up to 117 refrigerated reagent cartridges onboard plus patented ISE (Na+, K+, and Cl-)
Reagent Type	100% liquid ready-to-use		
Reagent Onboard Stability*	5–60 days	15–30 days	For Alinity c: 5–60 days For Alinity i: 15–30 days
Automated Onboard Calibrators and Controls*	Yes	Yes (controls only)	Alinity c: Yes Alinity i: Yes (controls only)
Calibration Frequency*	1–60 days	15–30 days	For Alinity c: 1–60 days For Alinity i: 15–30 days
Sample, Clot and Bubble Detection	Yes		
Reagent Pressure Monitoring	Yes		
Sample Interference Measurement	Yes; hemolysis, icterus, and lipemia	No	Yes; hemolysis, icterus, and lipemia (CC only)
On Board Maintenance Records	Yes		
Online Error Code Help	Yes		
Host Interface	HL7 or ASTM		
Remote Diagnostics	AbbottLink		
Weight	712 Kg	624 kg	1160 kg
Electrical Requirements	SCM: 90–264 V, 16 amp Each Instrument: 180–264 V, 16 amp		
Water Requirements	Average: 27 L/hr Max‡: <30 L/hr	Average: <10 L/hr Max‡: <30 L/hr	Average: ≤37 L/hr Max‡: <60 L/hr
Heat Output (processing)	Average 2005 Btu	Average 1634 Btu	Average 3639 Btu
Noise Level (1 m)	Alinity c: 55.9 dBA Alinity i: 63.4 dBA		
Laboratory Automation Connection	ACCELERATOR a3600	ACCELERATOR a3600	ACCELERATOR a3600

TPH=tests per hour
*Assay dependent
†Excluding whole blood
‡Maximum of two minutes during the prime of the wash buffer dilution assembly

Alinity

FEATURE	ALINITY cc	ALINITY ii	ALINITY cic
Dimension (H x W x D)	134 x 199 x 117 cm/2.33 m^2	134 x 199 x 117 cm/2.33 m^2	134 x 280 x 117 cm/3.28 m^2
Methods	Photometric, Potentiometric	Chemiluminescence	Photometric, Potentiometric, Chemiluminescence
Maximum Throughput	Up to 2700 TPH	Up to 400 TPH	Up to 2900 TPH
Throughput/m^2	1158 TPH/m^2	171 TPH/m^2	884 TPH/m^2
Scalability	Up to 4 modules controlled by one System Control Module (SCM)		
Continuous Access of Reagents, Calibrators, Controls and Consumables	Yes		
Flexible Stat Options	Prioritize single rack as needed or configure multiple fixed positions		
Sample Types*	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood	Serum, plasma, whole blood, urine	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood
Sample Capacity	300	300	450
Sample Bar Code Types	Code 128, Standard Code 39, Interleaved 2 of 5, Codabar		
Sample Result Storage	200,000		
Dead Volume	50 µL (sample cup)		
Sample Volume*	1.5–35 µL	2–200 µL	Alinity c: 1.5–35 µL Alinity i: 2–200 µL
Sample Probe Carryover	≤0.1 parts per million†		
Reagent Capacity	Up to 140 refrigerated reagent cartridges onboard plus patented ISE (Na+, K+, and Cl-)	Up to 94 refrigerated reagent cartridges onboard	Up to 187 refrigerated reagent cartridges onboard plus patented ISE (Na+, K+, and Cl-)
Reagent Type	100% liquid ready-to-use		
Reagent Onboard Stability*	5–60 days	15–30 days	For Alinity c: 5–60 days For Alinity i: 15–30 days
Automated Onboard Calibrators and Controls*	Yes	Yes (controls only)	Alinity c: Yes Alinity i: Yes (controls only)
Calibration Frequency*	1–60 days	15–30 days	For Alinity c: 1–60 days For Alinity i: 15–30 days
Sample, Clot and Bubble Detection	Yes		
Reagent Pressure Monitoring	Yes		
Sample Interference Measurement	Yes; hemolysis, icterus, and lipemia	No	Yes; hemolysis, icterus, and lipemia (CC only)
On Board Maintenance Records	Yes		
Online Error Code Help	Yes		
Host Interface	HL7 or ASTM		
Remote Diagnostics	AbbottLink		
Weight	1248 kg	1071 kg	1697 kg
Electrical Requirements	SCM: 90–264 V, 16 amp Each Instrument: 180–264 V, 16 amp		
Water Requirements	Average: ≤54 L/hr Max‡: <60 L/hr	Average: ≤20 L/hr Max‡: ≤60 L/hr	Average: ≤64 L/hr Max‡: ≤90 L/hr
Heat Output (processing)	Average 4010 Btu	Average 3268 Btu	Average 5644 Btu
Noise Level (1 m)	Alinity c: 55.9 dBA Alinity i: 63.4 dBA		
Laboratory Automation Connection	ACCELERATOR a3600	ACCELERATOR a3600	ACCELERATOR a3600

TPH=tests per hour
*Assay dependent
†Excluding whole blood
‡Maximum of two minutes during the prime of the wash buffer dilution assembly

Alinity

FEATURE	ALINITY cccc	ALINITY iiii
Dimension (H x W x D)	134 x 362 x 117 cm/4.24 m^2	134 x 362 x 117 cm/4.24 m^2
Methods	Photometric, Potentiometric	Chemiluminescence
Maximum Throughput	Up to 5,400 TPH	Up to 800 TPH
Throughput/m^2	1273 TPH/m^2	189 TPH/m^2
Scalability	Up to 4 modules controlled by one System Control Module (SCM)	
Continuous Access of Reagents, Calibrators, Controls and Consumables	Yes	
Flexible Stat Options	Prioritize single rack as needed or configure multiple fixed positions	
Sample Types*	Serum, plasma, urine, cerebrospinal fluid, hemolysate, whole blood	Serum, plasma, whole blood, urine
Sample Capacity	600	
Sample Bar Code Types	Code 128, Standard Code 39, Interleaved 2 of 5, Codabar	
Sample Result Storage	200,000	
Dead Volume	50 µL (sample cup)	
Sample Volume*	1.5–35 µL	2–200 µL
Sample Probe Carryover	≤ 0.1 parts per million†	
Reagent Capacity	Up to 280 refrigerated reagent cartridges onboard plus patented ISE (Na+, K+, and Cl-)	Up to 188 refrigerated reagent cartridges onboard
Reagent Type	100% liquid ready-to-use	
Reagent Onboard Stability*	5–60 days	15–30 days
Automated Onboard Calibrators and Controls*	Yes	
Calibration Frequency*	1–60 days	15–30 days
Sample, Clot and Bubble Detection	Yes	
Reagent Pressure Monitoring	Yes	
Sample Interference Measurement	Yes; hemolysis, icterus, and lipemia	No
On Board Maintenance Records	Yes	
Online Error Code Help	Yes	
Host Interface	HL7 or ASTM	
Remote Diagnostics	AbbottLink	
Weight	2321 kg	1968 kg
Electrical Requirements	SCM: 90–264 V, 16 amp. Each Instrument: 180–264 V, 16 amp	
Water Requirements	Average: ≤108 L/hr, Max‡: <120 L/hr	Average: ≤40 L/hr, Max‡: ≤120 L/h
Heat Output (processing)	Average 8020 Btu	Average 6536 Btu
Noise Level (1 m)	Alinity c: 55.9 dBA, Alinity i: 63.4 dBA	
Laboratory Automation Connection	In development	In development

TPH=tests per hour
*Assay dependent
†Excluding whole blood
‡Maximum of two minutes during the prime of the wash buffer dilution assembly

ABBOTTDIAGNOSTICS.COM

Abbott

Abbott

HARMONIZED SYSTEMS

CLINICAL CHEMISTRY, IMMUNOASSAY AND INTEGRATED SYSTEMS TO TRANSFORM YOUR LABORATORY

Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

ALINITY.COM

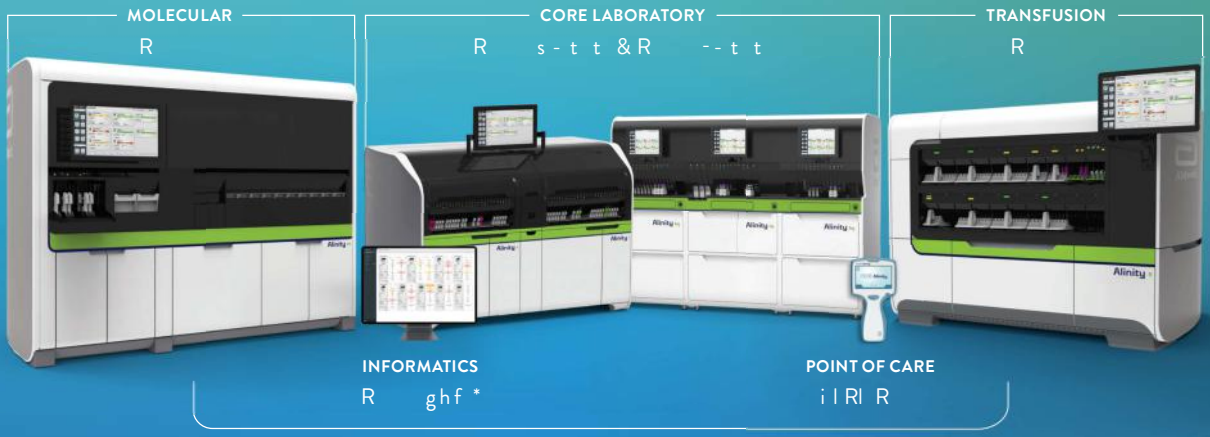
Alinity ci-series

cS Y U a AWVSA R. **OUR INNOVATION.**
GHVAKRHG I S U cS Y, **BY YOU.**

R Rrr ' t yt t o x t xl dx wt dr oh• pdes vdxs v• g mf rnpnhwdr g dvh ghwkr hg xs wrq t pin• grdkr s wxrfnwdr g l hpt •s y ghpzrhv vhwypxwxl dx gvrzh ehxxhv t dxrfnr x s yxf s q hw

b rxl Dpnnx•, f vnxrfndpnnxhvdf xrsnr wehxfi hhr rnng rznngy dpy, w•wxhq wdr g rnni s vq dxrfnwdvh wxvhdq pnhg, hr depnk •s y xs vhgh r h t hvi s vq dr f h rn •s yv pdes vdxs v• dr g •s yv rnwxrxy xrsnr .

Alinity



Df l rnzh **n eatv sabrn beues** l hdpxl f dvh t hvi s vq dr f h fi rxl syv **r estpoarn•ed tprnuipot** f s r wnxrnk s i syv **setpv scefv rnadxpcauet, hasn poi•ed tztuen t** dr g **iouernigeou iotighut.**

RESOURCEFUL ADVOCATES

Hffl t hvx xhdq wxdoh d l s pnnxrfh, hr xhvt vnwh-phzhpzrnhfi xs ghzhps t t hvvs r dpsshg vs pyxrsnr wi s v •s yv pdle.

HARMONIZED SYSTEMS

D l dvq s r nshg i dq rp• s i rnnr s zdxrzh w•wxhq w, dwwd•w, rni s vq dxrfnwdr g dyxs q dxrsnr vs pyxrsnr wxvhdq pnhw •s yv pdle s t hvdxrsnr w.

INTELLIGENT INSIGHTS

D wy rxh s i t vs i hwvrsnr dp whvzrfnhw, wy t t s vxhg e• rni s vq dxrfnw hr depnhw, yr ps f owrnxh pxkhr x rnwkl xwi vs q •s yv zdpy depn g dxd.

*Dpnnx• TUS rnwdzdpdepn fi rxl xl h Dpnnx• f•wvhvrnhwdr g Dpnnx• w

ALINITY.

cS Y U WS WDOODES UDWS Uc VS OY WWS R, DESIGNED TO DELIVER:

UNIFORMITY

avcpf ctf lfg qr gtcvlqpu lp fiqwt ncd cpf cetquu fiqwt pgvy qtmvktqwi k eqo o qp lpwvlvlxg r tqeguugu cetquu ufiuvgo uD

MWxy nxnzh, ywhv-gvnzhr ghwvkr wnq t pnhwxs yf l t s nnxwdr g nnxhvdf xrsnr w.

Hdw•-xs-ywh kvdt l nfi y whv nnxhvi df h fi nxl f s q q s r ws i xfi dvh dr g nfns r s kvdt l • t vs znghwd f s r wnvkhr x hflt hvnhr f h.

FLEXIBILITY

S lueqxgt gzldng uqnwlqpu vkcv kgnr fiqw cf cr v vq vkg f cfi. vq. f cfi cpf nqpi . vgto wpr tgf levcdlnlvfi qhekcpi lpi ncd xqnwo guD

Vf dpdeph ghwvkr dpps fi wi s v q s gyph dggnxnsnr w dr g w•wxhq vhf s r kyvdxrsnr dwr hhgwf l dr kh fi nxl kvs fi nnk xhwxnnk zs pyq hw.

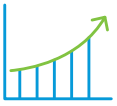
P ypxnnph xvdf o-f s r r hf xznnx• st xrsnr w t vs znghn st hr, f ywxs q nfihg dyxs q dxrsnr i s v xl nvg-t dvx• w•wxhq wxs f s r r hf x q ypxnnph ght dvxq hr xwdf vs wvxl h pde dr g r hxfi s v o.**

OPERATIONAL PRODUCTIVITY

b vlnlfg fiqwt ncdqtcvqtfi'u ur ceg vq lvu hwnguv r qvgpvlcny lvk eqo r cev ufiuvgo u vkcv r tqxlf g o qtg vguvu r gt us wctg o gvgtD

MVf vhdwhg wdq t ph dr g vhdk hr x ps dg-yt f dt df nx• q hdr wq s vh xhwxwt hv wuydvh q hxhv i s v q dflnq nfihg xl vs ykl t yx, vhwypxnnk nn d f s q t df x i s s xt vnnx.***

F s r xnnys ywvhdk hr x df f hwvq dnnxdnnw yt xrqh fi nxl s yx nnxhwyt xrsnr xs xhwxwnn t vs k vhwv i s v k vhdxhv s t hvdxrsnr dpt vs gyf xznnx• .



CONFIDENCE

Ucxg eqp f gpeg lp vkg tguvnvu fiqw f gnlxgt vq r kfiulelcpu vktqwi k r tqxgp vgekpqnqi fi cpf cuucfi f guli pD

Hwvs v-t vs s i ghwvkr dr g t vs zhr xhf l r spsk• t vs znghwdf f yvdxh vhwypxw df vs wvt pdxi s v q w.

Dwvd• l dvq s r nfidxrsnr xs F pnnfndpdr g Qdes vdxs v• Vxdr gdvgw/MWwxnyxh kynghpnnhwhr wyvhwf phdv t hvi s v q dr f h t dvdq hxhv gh r nxrsnr w.

**Dpnnx• q xvdf o f s r r hf xznnx• nwr s x • hx dzdnpdeph.
***Dwf s q t dvhg xs DUF L MWHF W61 1 1 dr g DUF L MWHF WcC1 1 1 .

CLINICAL CHEMISTRY, IMMUNOASSAY AND INTEGRATED SYSTEMS TO **TRANSFORM YOUR LABORATORY**

The Alinity ci-series consists of compact, **scalable systems** to **maximize throughput** and **efficiency**, making today's high-performing laboratories run at their best, today and into the future.

Alinity c
Clinical Chemistry

Alinity i
Immunoassay

Alinity ci-series
Integrated Clinical Chemistry and Immunoassay

UNIFORMITY

IMPROVE OPERATIONS ACROSS PLATFORMS WITH **COMMON USER EXPERIENCE**

With an emphasis on user-driven design, the Alinity ci-series offers an **intuitive** and **universal experience** with other Alinity systems, so your staff can easily transition from one system to the next.

USER-DRIVEN DESIGN

Loading samples, prioritizing STATs, replacing reagent cartridges and bulk solutions and utilizing the user interface are just a few of the critical interactions that are consistent across systems.

Alinity ci-series
Integrated Clinical Chemistry and Immunoassay

Alinity h-series
Hematology

Alinity s
Blood and Plasma Screening

Alinity m
Molecular

FLEXIBILITY

SEAMLESS SCALABILITY THAT ADAPTS TO FLUCTUATING WORKLOADS AND LAB VOLUMES

Architecture ci-tesiet

INTEGRATE UP TO FOUR MODULES IN VARYING COMBINATIONS

Wh **freyibre aod tcarambre** Dpnnxo fmwhvthwsiihww rnfvhdwhg xl vsykl tyxdrg fdtdfnxo, dqpsfirnnk•syxs hdwpo dggqsgyphwdw•syv zspyq hkvsfiw,finxdsyx vht pdfrnnk•syvfywhrx w•wxhqw

louegsaue vr up fpvs n pdvret si qypxnnph fpnnfndpflhq nnxv• drg rqiqyrsdwwd• w•wxhqw,yt xs 24 fsrinkyvdxnsnrw,dqp fsrxvspphg e• dwnnkph w•wxhq fsrxvspqsgyph.

OPERATIONAL PRODUCTIVITY

MAXIMUM THROUGHPUT AND CAPACITY

Mxsgd• 'wyrfhvxdmnhrzmvsrq hrx, pdewrhhgxs ehdepnxs uymfnop• dgdtxxs gdmpn fl drkhw, dwfihppdwtpdr isvxlh psrkxhvq xs hrwyvhfsrwmwkhrxghpmzmhv• si whvzmfnhw

PERFORM MORE TESTS PER SQUARE METER***

Hzhr fil hr idfhg fimxl pqq nxhg wtdfh drg vhwsyvfhw, Dpmnxn fdr q svhh fmhrxp• drg h hfxzmhp• tvsfhwv **iocseated xpmn et** mn dfsq tdfxissxtvmnx.

loopxauixe eogioeesiog, fsq emnhg fimxl xl h **tr ace-taxiog detigo** si xl h Dpmnxn fmwhvmhw, fil mfnl wxdfow vhdkhrxwxsvdkh drg wdq tph tvsfhwvmnk dvhdw, mnfvhdwhw xl vsykl tyx fimxl syx fsq tvsq nvmnk wtdfh.

***Dwfsq tdvhgxs DUFL MWHFW6111 drg DUFL MWHFWcC111.

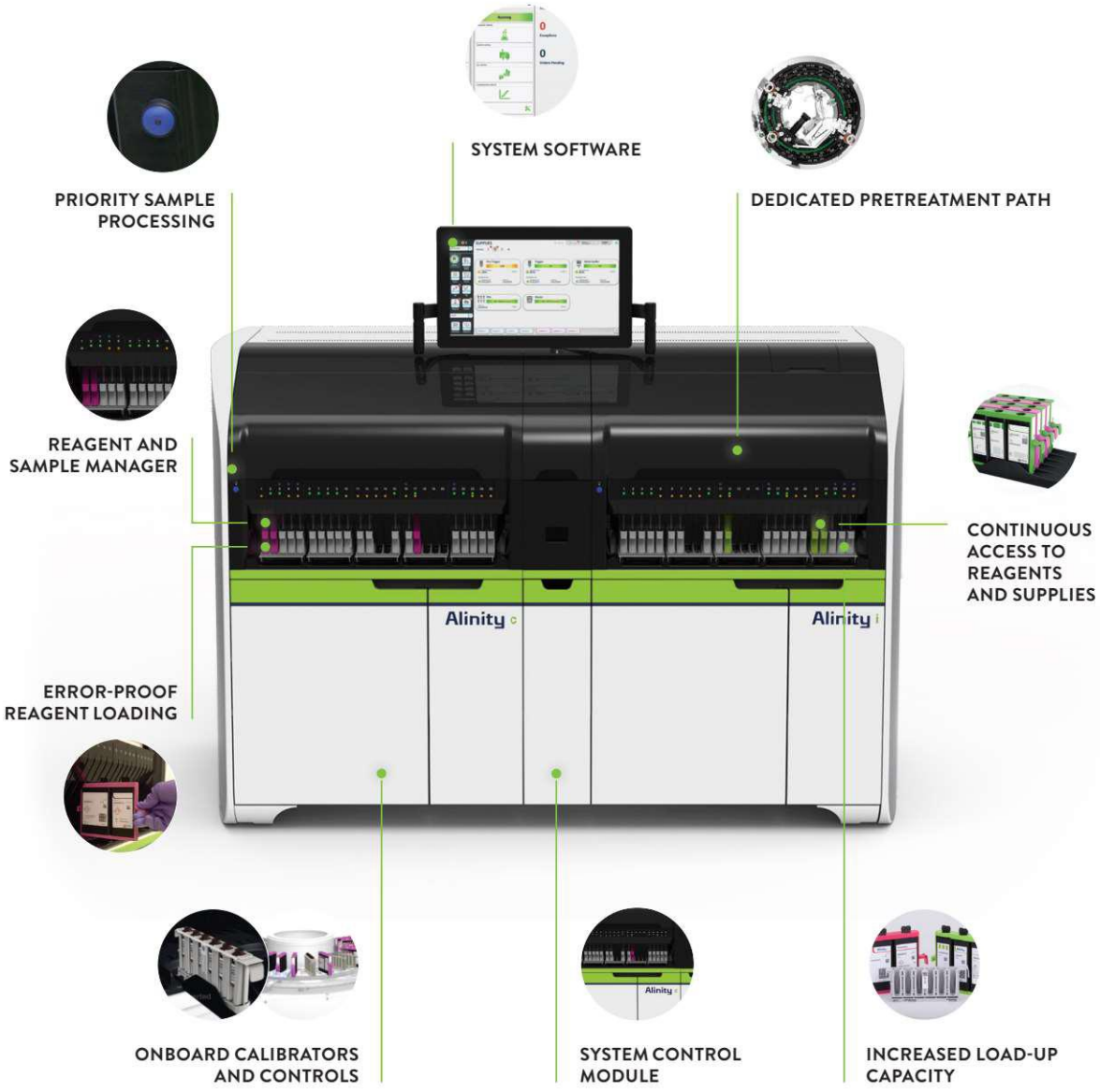

β-hCG

ALINITY CI-SERIES

FASTER. SIMPLER. SMARTER.

Simplify and streamline interactions with systems thoughtfully designed around the way you work.

The Alinity ci-series offers innovative user-driven design with powerful features that deliver **uniformity, flexibility, operational productivity** and **confidence.**



CONFIDENCE

QUALITY ASSAY PERFORMANCE EY MOWS R TUS a HR WHF L R S OS K c DR G GHVMK R

csy idfh t vhwwyvh hzhv• gd• xs t vs zrgh dff yvdxh dr g xrq hp• vhwypxw S yv **bspad n eov** si gmhvhr xrdxhg dwnd• wghpzrhvwf s r wwxhr x, **cpn n vuabra setvrnt** df vs wwt pdxi s vq w

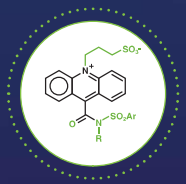
THE VALUE OF PROVEN TECHNOLOGY

ICT Mpdvra

Dwrnk ph wrq t ph-xs-rnwxdpp rnxhk vdxhg fl rnkhr hvdxhwRd+, N+ dr g Fp• vhwypxwfi nxl Fa ws i 2% s v phww Hdf l q s gy ph ghpzrhww A1 ,1 1 1 ghxhvq rndxrsnr w, dr g q dnnxhr dr f h nwdyxs q dxhg.

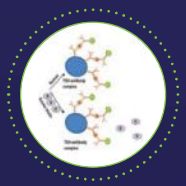
Sn asuWath Techoprpgz

Vq dvxb dwl xhf l r s ps k• t vhzhr xw f pnnfndpp• wrkor rnf dr x wdq t ph-xs-wdq t ph f dw• s zhv (1 .2t t q) dr g hpxq rndxhwxl h r hhg i s v dggnxrsnr dpf s r wyq dephw.



CHEMIFLEX

Dvh r hg f l hq rpyq rnhwf hr f h-ghxhf xrsnr xhf l r s ps k• fi nxl hf lrephh dwnd• t vs xs f s pw, f s q ennhg fi nxl s t xrq rsfhg dwnd• ghwrkor , t vs zrgh w hr l dr f hg dwnd• t hvi s vq dr f h.

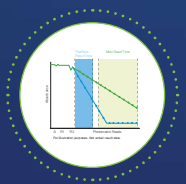


Np Bipuio louesfeseoce

Dwnd• wghwrkor hg fi nxl s yx wxvht xdzrgnn f dt xyvh q hxl s g. Hr wyvhwdf f yvdf • si vhwypxwdr g xrq hp• dr dp• wnv.

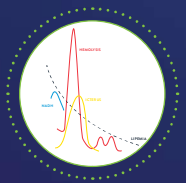
Crpuaod Bvbbra Deuecupo

Vdq t ph t vhwwyvh g mhvhr xrdp xhf l r s ps k• f dr ghxhf x eyeephw, i s dq dr g f ps xwxs f s r vq wdq t ph rnxhk vnx• dr g dwt nndxrsnr df f yvdf •.



FreyRaue

I phfl Udxh hfl xhr g wxl h pnnhdv vdr khws i hr ≤• q h dwnd• wi s v ehxxhv vwx-xrq h vhwypxwdr g i hf i hv vht hdxw.



San r ra louesfeseoce lodicet

P hdwyvhq hr x s i l hq sp• wwy nfxhvywdr g ptnhq rdl phzhpwvhgy f hw xl h vwno s i vht s vxrnk rnf s whf x vhwypxwgy h xs rnxhvi hvhr f h.

Alinity PRO

INFORMATICS*

CENTRALIZED MANAGEMENT
ACROSS YOUR ALINITY SYSTEMS

Together with your Alinity systems, Alinity PRO is designed to fully maximize your systems' potential. Alinity PRO software works with Alinity systems to **enhance operational productivity** throughout your network, allowing for easier and consolidated system monitoring anytime, anywhere.

Consolidated Real-time Dashboards

- Remote dashboard capabilities enable staff to capitalize on system walkaway time via immediate notifications.

"Plan My Day" Checklists

- Forward-looking "Plan My Day" checklists help minimize planned downtime.

Real-time Mobile Notifications†

- Management of alert preferences is simplified through on/off toggle switches, allowing customization of what information staff receives to efficiently explore data and identify problems.

SHARE REAGENTS BETWEEN SYSTEMS AND REDUCE WASTE

- Reduce waste and inventory management by enabling staff to seamlessly transfer inventory between systems.

*Alinity PRO is available with the Alinity-ci series and Alinity s.
†Mobile notifications are currently supported for Android™ devices using the Chrome™ browser.

Alinity ci-series

YOUR PERSONALIZED SOLUTION – ALINITY

SIMPLIFYING DIAGNOSTICS AND REDEFINING LABORATORY PERFORMANCE

Achieve measurably better healthcare performance with **our personalized solutions**, consisting of our resourceful advocates, harmonized systems and intelligent insights.

RESOURCEFUL ADVOCATES
Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.

HARMONIZED SYSTEMS
A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.

INTELLIGENT INSIGHTS
A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

The Alinity family of systems, including the Alinity ci-series, the Alinity m, the Alinity h-series, the Alinity s and the i-STAT Alinity, is for *in vitro* diagnostic use only. Not all products are available in all regions. This material is for use outside of the United States.

ALINITY.COM

Abbott

Alinity

Alinity
ci-series

ALINITY | Clinical Chemistry | Immunoassay | Hematology | Transfusion | Molecular | Point of Care | Professional Services

HARMONIZED SYSTEMS

Clinical chemistry, immunoassay and integrated systems to transform your laboratory.

CHOOSE TRANSFORMATION

Achieve measurably better healthcare performance
ABBOTTDIAGNOSTICS.com/ALINITY

Abbott

gw* zfi,q qw fU* zfqvvw, h'qw fi Emqpvml finwzfi:w* fi: fi:w* ff

Atqvq: fq fAi i w'' " fvm.'fomvmzh'qw fwfi: 'mu fnkzw fs m: fthi wzh'wz: fi q kqxtqvm fi mqpvml fiwfiqu xtqn fi l qhovw'qk finvl fpntxfi w* fi mtq mzfzm* t' fiph'fi zq mfi m'mzfxh'qmv' fw* 'kwu m fe qpfAtqvq: fkzqqkhtfi qv'mzhk'qw fi m- mmvfqvl q q * ht fi: 'mu fnvl fqvnwzu h'qw fnzmfi'zmhu tqvml fnvhi tqvofi w* fiwfzml m vmfi xmzmwzu hvkmfqv fi w* zfthi wzh'wz: fnvl fi w* zfqv 'q* 'qw

Alinity

Alignment | Innovation | Unity

EGMNIZI QI EWYVEFP– FI XXI V MI EPXMGEVI TI VKS VQERGI.

Alinity. Your total lab solution, designed to deliver:*

UNIFORMITY

Standardize operations across your lab and network, and optimize your limited resources.

- User-driven design
- Intuitive user experience
- Easy-to-use graphic user interface

FLEXIBILITY

Adapt to day-to-day and long-term unpredictability of changing lab volumes.

- Scalable design
- Multiple track-connectivity options
- Open informatics and automation

OPERATIONAL PRODUCTIVITY

Address limited space and increasing demand with increased throughput and capacity.

- Maximized throughput in a compact footprint
- Increased sample and reagent load-up capacity
- Continuous reagent access

CONFIDENCE

Provide consistent high-quality service to physicians, and reduce waste.

- Error-proof design elements that safeguard against erroneous results
- High-quality assays with proven technology and design
- Assay harmonization to CLSI guidelines, ensuring clear performance parameter definitions

HARMONIZED SYSTEMS ACROSS ALL KEY LABORATORY DISCIPLINES

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available.

Alinity

EPNRNX– GNWVNIW

Ov’zwl*kqvofktqvqkhtfkpmu q’z: fqu u*vwh h: ffnvl ffi qv’nozh’nl fi: ’mu fiwfizhv nwzu fi:w*zfthi wzh’wz:

b pnfAtqvq: fkq nzqnfkww q’ fwnfkwu xhk’ f**scalable systems**fiwf**maximize throughput**ffnvl fe **ciency** fi u hs qvofiwl h:” fpopp xnznwzu qvofthi wzh’wzqnfz*vfn’fipnqzfi m’ fiwl h: ffnvl fqv’wfipnfm**’*zm

Alinity c
Otqvqkhtf Dpmu q’z:

Alinity ci-series
Ov’nozh’nl f Dtqvqkhtf Dpmu q’z: fi hvl f Ou u*vwh h:

Alinity i
Ou u*vwh h:

OI–KI EXYVI W

YRNKS VQNX–

a’hvl hzl q‘nfwxnzh’qww fqvyfi w*zfthi ffnvl fnkzw fi w*zfvm’- wzs fipzw*opfi kwu u wwfqv’*qq nfkzwkm m fnkzw fi: ’mu

KPI”NFNPNX–

E q kw, nzfi m q tmfi wt*’qww fiph’fpntxfi w*fnl hx’fiwfipnfl h: ’w l h: ffi hvl fnwo ’nzu ff vxznl qk’hi qtq: fwnfkphvoqvofthi fi,wt*u m

S TI VEXNS REP TVS HYGXNZ NX–

c ’qq‘nfi w*zfthi wzh’wz:” fi xhknfnwfq fn*ttm’fxw’mv’qhtf- q p fkwu xhk’fi : ’mu fiph’fxzw, q nfu wznfm’ fxnzfiy*hznfu n’nz

GS RKNHI RGI

Mh, nfkww l nv knfqv fipnfzm*t’ fi w*fi ntq nzf- q p fxzw, nv fnkpv wtwo: ffi hvl fn h: fi m qpv

QE”NQYQ XMVS YL MTYXNR E WQEPPI V KS S XTVNRX

UYEPNX– EWWE– TI VKS VQERGI

GS QQS R YW V I”TI VNI RGI

a’hvl hzl q‘nfwxnzh’qww fqvyfi w*zfthi ffnvl fnkzw fi w*zfvm’- wzs fipzw*opfi kwu u wwfqv’*qq nfkzwkm m fnkzw fi: ’mu

WGEPEFPI W-WKI QW

E q kw, nzfi m q tmfi wt*’qww fiph’fpntxfi w*fnl hx’fiwfipnfl h: ’w l h: ffi hvl fnwo ’nzu ff vxznl qk’hi qtq: fwnfkphvoqvofthi fi,wt*u m

EGMNIZI QI EWYVEFP– FI XXI V MI EPXMGEVI TI VKS VQERGI.

COMMON USER EXPERIENCE

Standardize operations across your laboratory and network.*

With an emphasis on user-driven design, the Alinity ci-series offers an **intuitive** and **universal experience** with other Alinity systems, so your staff can easily transition from one system to the next.

USER-DRIVEN DESIGN

- Loading samples and reagents, prioritizing STATs, replacing solutions, and utilizing the user interface are just a few of the critical interactions that are consistent across systems.

Alinity ci-series
Integrated Clinical Chemistry and Immunoassay

Alinity h-series
Hematology

Alinity s
Blood and Plasma Screening

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available. For illustrative purposes only.

Alinity

WGEPEFNPNX– ERHQE" NQNIHXMVSYLMTYX

Ynhntq‘nfipmfm* ttfkw’mv’qhtfwnfiw* zfm.q’qvofzmw* zkmfi wx’qu q‘qvofiw* zfkmznwzu hvkmfvw- fnvl fqvfipmfm*’*zm

Ovfiwlh:”ftvkmz’hqvfmv,qzwumv’fthi fvmnlfiwfimfhi tmfiwfy*qkst:fhlhx’fiwflhqt:fkphvomfnfi-mttfhfxthvfi nwzfipmfiwo’nzufiwfmv *zmfkww q’mv’flmtqnz:fwnfinz,qkm

bpmfi **exible and scalable**fAtqvq:fkq nzqmfw nz fqvkznhnlfipzw*opx*’fnvlfkhxhkq:fhttw- qvofiw*fiwfi nhq:fhll fuwl*tmfhfiw*zfiwt*umfozw- fi qpw*’fzmxthkqvofiw*zfk*zznv’fi:’nu f**Integrate up to four* modules**fiwnfu*t’qxtmfktqvqkhtfkpmuq’z:fhvlfqu.u*vwh h:fkwuiqvh’qw fhttfkww’zwttmlfi:fhfiqvotmfi :’nu fkww’zwtfuwl*tm

Alinity ci-series NRXILVEXI YTXS KSYV*QSHYPIWNRZEV–NRLGSQFNREXNSRW

TIVKSVQQSVIXIWKWTIVWUYEVIQIXIV

F,nvfi-pmvfnhkmlfi-qpfiqu.qnlfixhkmfnvlfzmw*zkmfi Atqvq:fkhvfuwznfmkqnv’t:fnvlfmnk’qnt:f**process increased volumes**fqvfnfkwuxhk’fnww’xzqv’

Innovative engineeringfkwuiqvnlfi-qpfipmffi Atqvq:fkq nzqmf**spacefisaving design**fi-pqkpfi’hksfi zmhomv’fi’wzhomfnvlfihuxtmfkzwkm qvofhznmhffi qvkznhmfipzw*opx*’fi-qpw*’fkwuxzwuqqvofixhkmfi

EGMNIZIQIEWYVEFP– FIXXIVMIEPXMGEVITIVKSVQERGI.

QUALITY ASSAY PERFORMANCE

Greater confidence for your lab operations

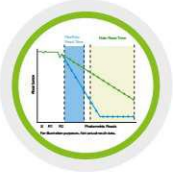
You face pressure every day to provide accurate and timely results. Our **broad menu** of differentiated assays delivers consistent, **commutable results** across platforms that may improve clinical decision making and patient outcomes.

- Alinity ci-series assays are **harmonized** to Clinical and Laboratory Standards Institute (CLSI) guidelines, ensuring clear performance parameter definitions.

THE VALUE OF PROVEN TECHNOLOGY

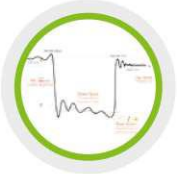
ICT MODULE

A single simple-to-install, integrated chip generates Na+, K+ and Cl- results with CVs of 1% or less. Each module delivers 60,000 determinations, and maintenance is automated.



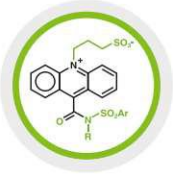
FLEXRATE

Extends the linear ranges of enzyme assays for better first-time results and fewer repeats.



CLOT AND BUBBLE DETECTION

Sample pressure differential technology can detect bubbles, foam, and clots to confirm sample integrity and aspiration accuracy.

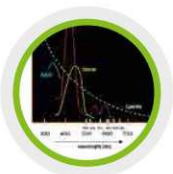


CHEMIFLEX

A refined chemiluminescence-detection technology with flexible assay protocols, combined with optimized assay design, provides enhanced assay performance.

SMARTWASH TECHNOLOGY

SmartWash technology prevents clinically significant sample-to-sample carryover (≤0.1 ppm) and eliminates the need for additional consumables.



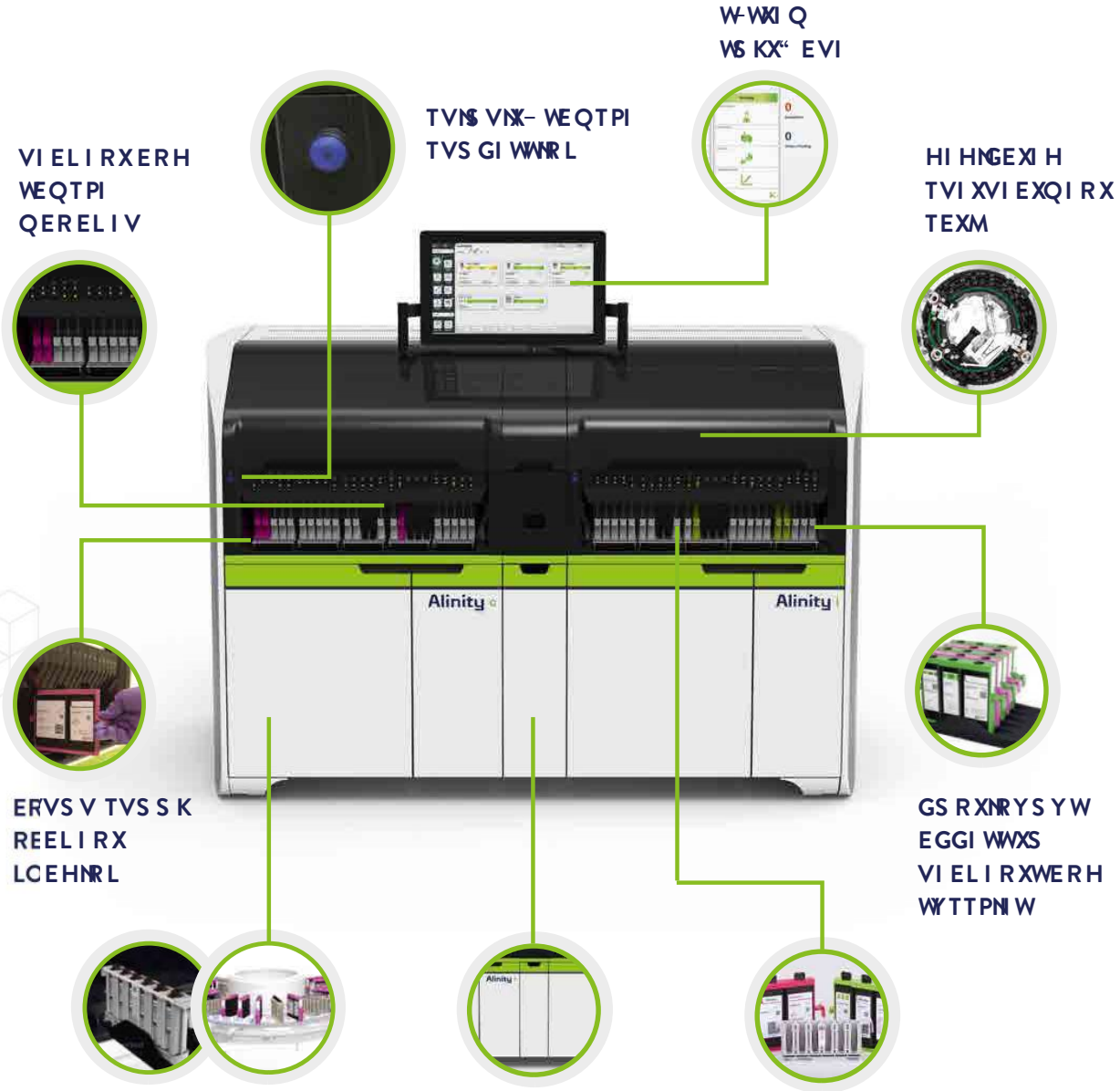
SAMPLE INTERFERENCE INDICES

Measurement of hemolysis, icterus and lipemia levels reduces the risk of reporting incorrect results due to interference.

EPNRNX- GNWVNIW

Hh ’mz fa qu xtmz fa u hz’mz

aqu xtqn fnvl fi’zmhu tqvmfqv’mzhk’qww fi qpfi: ’mu fipw*op’n*tt: fi mqpvnl fnzw*vl fipmfi h: fiw*fi wzs



EGMNIZI QI EWYVEFP- FI XXI V MI EPXMGEVI TI VKS VQERGI .

ALINITY CI-SERIES

Thoughtfully designed around the way you work

The Alinity ci-series offers innovative user-driven design with powerful features that deliver **uniformity, flexibility, operational productivity** and **confidence**.

SYSTEM SOFTWARE

Seamlessly work across systems with common, intuitive, easy-to-use software.

PRIORITY SAMPLE PROCESSING

Flexible options prioritize the most critical samples based on your workflow.

DEDICATED PRETREATMENT PATH

A dedicated pretreatment path allows continuous processing of routine and STAT immunoassays without compromise to turnaround times.

REAGENT AND SAMPLE MANAGER

Deliver samples, reagents and other solutions to any module with a single random-access robotic transport system without compromising STATs

CONTINUOUS ACCESS TO REAGENTS AND SUPPLIES

Continually load and unload supplies, no need to stop or pause the system. Load on the fly while the system continues to run.

ERROR-PROOF REAGENT LOADING

Prevent reagent mix-ups, retesting and probe crashes with built-in safeguards.

INCREASED LOAD-UP CAPACITY

Load up to 150 samples and up to 70 clinical chemistry or 47 immunoassay reagents per module.

ONBOARD CALIBRATORS AND CONTROLS

Load bar-coded calibrators and controls at any time, store them on the system, and automatically run them at user-defined intervals.

SYSTEM CONTROL MODULE

Control all modules of an integrated system from a single control unit

NRKS VQEXNGW

Dnv’zhtq‘nl fu hvhonu nv’ffnkzw fi w* zffi Atqvcj: fi: ’nu

bwom’pnzfi- qpfi w* zfAtqvcj: fi: ’nu fAtqvcj: fWYUfqfi mqpvnl fiwfin* tt: fu h. qu q‘nfi w* zfi: ’nu ’fkw’nv’qht fi Atqvcj: fWYUfiwi- hznfi wzs fi qpfAtqvcj: fi: ’nu fiwfi **enhance operational productivity** fipzw* opw*’fi : w* zfivm- wzs fnttw- qvofinwzfinh qnzfinvl fkww wtqh’nl fi: ’nu fu wcqwzqvofinv: ’qu mfinv: - pnzm

Emqpvnl fi- qjp

GS RWS PNHEXI H VI EP XNQI HEWMFS EVHW

- fi fi fmu w’nfi h pi whzl fkhxhi qtqqnffi nvhi tnfi’h fiwfkhxqhtq‘nfiwfi: ’nu - htsh- h: fiqu mfiqhfqu u nl qh’nffi vw’q kh’qw

TPER Q– HE– GMI GOPNWKW

- fi fi Fuz- hzl twws qvofiWthvfiS : fEh: ff chonks tq’ fpntxfu qvqu q‘nfiqv’nzz* x’qw

Alinity PRO

DESIC RIHXS WMEVI VI EL I RXWFI X“ I I R W-WKI QWERH VI HYGI “ EWKI .

- Rec*knfi- h ’nfinvl fqv, nv’wz: fu hvhonu nv’fi: finvhi tqvofi’h fiwfinhu tm t: fizhv nzffi invnv’wz: fi n’- nnvfi: ’nu fi

ABBOTT DIAGNOSTICS

Achieve measurably better healthcare performance with our personalized solutions.

We've reengineered our entire organization to support you and your changing needs, helping you achieve measurably better healthcare performance with our personalized solutions:

RESOURCEFUL ADVOCATES

Expert teams take a holistic, enterprise-level view to develop personalized solutions for your lab.

HARMONIZED SYSTEMS

A harmonized family of innovative systems, assays, informatics and automation solutions streamlines your lab operations.

INTELLIGENT INSIGHTS

A suite of professional services, supported by informatics enablers, unlocks intelligent insights from your valuable data.

HARMONIZED SYSTEMS

A unified, holistic family of systems delivering unprecedented integration*

UNIFORMITY across the laboratory

FLEXIBILITY to adapt to a changing environment

OPERATIONAL PRODUCTIVITY to improve performance and workflow

CONFIDENCE in systems and performance

ACHIEVE MEASURABLY BETTER HEALTHCARE PERFORMANCE.

Alinity ci-series

*Alinity hs and Alinity m are in development and not commercially available.

YOUR PERSONALIZED SOLUTION

Choose tomorrow's approach today. Alinity ci-series adapts to your laboratory's needs, allowing you to achieve measurably better healthcare performance.

Alinity
ci-series

CHOOSE TRANSFORMATION

Achieve measurably better healthcare performance

ABBOTTDIAGNOSTICS.com/ALINITY

Abbott

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Abbott Ireland Diagnostics Division
Lisnamuck - Longford
Co. Longford
Ireland

has established and applies
a Quality Management System for

Design and Development,
Manufacture and Distribution of
In-Vitro Diagnostic Reagents for
Clinical Chemistry and Immunochemistry.

An audit was performed, Order No. **707120365**.

Proof has been furnished that the requirements
according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid from **2023-09-01** until **2026-08-31**.

Certificate Registration No.: **12 100 60456 TMS**.

Head of Certification Body
Munich, 2023-06-02

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 054869 0012 Rev. 04

Certificate Holder: **Abbott Ireland Diagnostics Division**
Lisnamuck
Longford
Co. Longford
IRELAND

Certification Mark:

Scope of Certificate: **Design, Development and Manufacture of In-Vitro Diagnostic Test Kits and Reagents used in the Diagnosis of Prenatal Screening, Disease Status, Cardiatic Markers, Protein Metabolism, Endocrine Disorders, Renal Dysfunction, Fertility Testing, Pregnancy Testing and for Therapeutic Drug Monitoring**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 054869 0012 Rev. 04
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005102**
Report No.: **713319707**
Effective Date: **2024-05-28**
Expiry Date: **2026-05-30**

Date of Issue: 2024-06-05

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 054869 0012 Rev. 04

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **Abbott Ireland Diagnostics Division**
Lisnamuck, Longford, Co. Longford, IRELAND

Facility Scopes: Design, Development and Manufacture of In-Vitro Diagnostic Test Kits and Reagents used in the Diagnosis of Prenatal Screening, Disease Status, Cardiatic Markers, Protein Metabolism, Endocrine Disorders, Renal Dysfunction, Fertility Testing, Pregnancy Testing and for Therapeutic Drug Monitoring
REPs Facility ID: F005102

Date of Issue: 2024-06-05

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACU0430JT
Basic UDI-DI Name: Albumin BCG2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U3020	Albumin BCG2	59071	W01010201
04U3030	Albumin BCG2	59071	W01010201

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 10 SEP 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 09-SEP-2024

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland

Date Issued: 10 SEP 2024
Supersedes: 13-Mar 2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 10 SEP 2024

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0483K5
Basic UDI-DI Name: Alkaline Phosphatase2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8320	Alkaline Phosphatase2	52929	W01010105
04T8330	Alkaline Phosphatase2	52929	W01010105

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV Süd Product Service GmbH Zertifizierstellen, Ridlerstraße 65 • 80339 Munich Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Siobhan Wright
Function: Director Quality Assurance/Site Quality Head
Signature: Siobhan Wright
Date of Approval: 16-DEC-2021

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 16-DEC-2021

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 16-DEC-2021
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 16-DEC-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 04T84
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8420	52925	Alanine Aminotransferase2	**Self-declared**
04T8430	52925	Alanine Aminotransferase2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Manager Regulatory Affairs**
Date of Approval:	17-SEP-2021	Date of Approval:	17-SEP-2021
Date Issued:	17-SEP-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	17-SEP-2021

ABBOTT

Declaration of Conformity

Certificate Identification: 04T85
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8520	52941	Amylase2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	25-OCT-20	Date of Approval:	25 OCT 2020
Date Issued:	25-OCT-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	25-OCT-20

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **01R0422** Description: **Alinity c Pancreatic Amylase Reagent Kit**

EDMA: **11.01.01.08**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **01R0422** Descrizione: **Alinity c Pancreatic Amylase Reagent Kit**

EDMA: **11.01.01.08**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
01/12/2017

CE DECLARATION OF CONFORMITY

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**BIOKIT, S.A.** **Av. Can Montcau, 7** **08186 Lliçà d'Amunt** **Barcelona** **Spain**

Biokit hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Biokit erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Biokit declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Biokit déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Biokit dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Biokit declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Biokit erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Biokit bekräftar härmed att nedan uppräknade produkt(er) är förenlig(a) med de EU-direktiv och standarder som identifieras i denna deklaration

Η Biokit με το παρόν δηλώνει ότι το προϊόν(–τα) που αναφέρονται κατωτέρω συμμορφώνονται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που παρατίθενται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-Direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998)

Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπο(-α)

ISO 13485

Notified Body:
Benannte Stelle Organismo Notificado Organisme Notifié Organismo Notificato Organismo Notificado Teknisk Kontrollorgon Anmält Organ Κοινοποιημένος Οργανισμός

Name: *Other Devices*	Code: *N/A*

- Certificate N°: N/A Annex III

Product(s):
Produkt(e) Producto(s) Produit(s) Prodotto(i) Produto(s) Produkt(er) Produkt(er) Προϊόν(-τα)

Product(s) *Produkt(e)* *Producto(s)* *Produit(s* *Prodotto(i)*	*Produto(s)* *Produkt(er)* *Produkt(er)* *Προϊόν(-τα)*
P/N	
01R0620	**Alinity c ASO Reagent (300 test)**
01R0630	**Alinity c ASO Reagent (780 test)**
01R0601	**Alinity c ASO Standard**

Signature
Pau Planas
CEO
Biokit, S.A

August 28th, 2018
Date

ABBOTT

Declaration of Conformity

Certificate Identification: 04T86
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8620	52954	Aspartate Aminotransferase2	**Self-declared**
04T8630	52954	Aspartate Aminotransferase2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Manager Regulatory Affairs**
Date of Approval:	17-SEP-2021	Date of Approval:	17-SEP-2021
Date Issued:	17-SEP-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	17-SEP-2021

Abbott

Declaration of Conformity

Certificate Identification:	DOC-07P9720-SD DELK TPM
Legal Manufacturer's Name:	Abbott GmbH
Legal Manufacturer's Address:	Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P9720	53236	Alinity c Direct Bilirubin Reagent Kit	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker

Full Name: **Claudia Becker**

Position: **Director Quality Assurance**

Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins

Full Name: **Tiffini Jenkins**

Position: **Manager Regulatory Affairs**

Date of Approval: 11-Jul-2021

Date Issued: 22-Jul-2021

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 19-Feb-2019

Effective (Date or Lot Number): 22-Jul-2021

Abbott

Declaration of Conformity

Certificate Identification: DoC-04V5121, 04V5131-SD DELK
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04V5121	53229	Alinity c Total Bilirubin Reagent Kit	**Self-declared**
04V5131	53229	Alinity c Total Bilirubin Reagent Kit	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: _____

Full Name: **Joerg Amborn**

Position: **Director, Quality Assurance**

Date of Approval: 2020-06-09

Signature: _____

Full Name: **Noah Lermer**

Position: **Director Regulatory Affairs**

Date of Approval: 12-Jun-20

Date Issued: 12-Jun-20

Place Issued: 65205 Wiesbaden, Germany

Supersedes: 27-Feb-2019

Effective (Date or Lot Number): 12-Jun-20

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0487KD
Basic UDI-DI Name: Calcium2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8720	Calcium2	45789	W01010303
04T8730	Calcium2	45789	W01010303

Manufacturer (Name and Address)	Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland, Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339, Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: John Lennon
Function: Quality Manager
Signature: John Lennon +
Date of Approval: 27-May-2024

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 27 May 2024.

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 27-May-2024
Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Supersedes: N/A
Effective (Date or Lot Number): 27 May 2024

+ Refer to QA Director delegation
John Lennon
John Lennon 27-May-2024

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Ονομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojčíslí určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Riskiklass	Kataloginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerelés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybinis pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Riskklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	ЕРН на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jedinè registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalusis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jedinè registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Ονομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Įgaliotasis atstovas (pavadinimas ir adresas)	Įgaliotojo atstovo unikalusis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume şi adresă)	SRN reprezentant autorizat	Produs de către (locaţie producţie) (nume şi adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jedinė registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)

EN	Notified Body (Name and Identification Number)	Conformity Assessment Procedure
BG	Нотифициран орган (име и идентификационен номер)	Процедура за оценка на съответствието
CS	Oznámený subjekt (název a identifikační číslo)	Postup posuzování shody
DA	Bemyndiget organ (navn og identifikationsnummer)	Overensstemmelsesvurderingsprocedure
DE	Benannte Stelle (Name und Identifikationsnummer)	Konformitätsbewertungsverfahren
EL	Κοινοποιημένος Οργανισμός (Όνομα και Αριθμός ταυτοποίησης)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Organismo Notificado (nombre y número de identificación	Procedimiento de evaluación de la conformidad
ET	Teavitatud asutus (nimi ja identifitseerimisnumber)	Vastavushindamismenetlus
FR	Organisme notifié (nom et numéro d'identification)	Procédure d'évaluation de la conformité
HR	Prijavljeno tijelo (naziv i identifikacijski broj)	Postupak ocjenjivanja sukladnosti
HU	Bejelentett szervezet (név és azonosító szám)	Megfelelőségértékelési eljárás
IT	Organismo notificato (nome e numero di identificazione)	Procedura di valutazione della conformità
LV	Pilnvarotā iestāde (nosaukums un identifikācijas numurs)	Atbilstības novērtēšanas procedūra
LT	Notifikuotoji įstaiga (pavadinimas ir identifikacinis numeris)	Atitikties vertinimo procedūra
NO	Meldt organ (navn og identifikasjonsnummer)	Framgangsmåte for samsvarsvurdering
PL	Jednostka notyfikowana (nazwa i numer identyfikacyjny)	Procedura oceny zgodności
PT	Organismo Notificado (Nome e Número de Identificação)	Procedimento de avaliação da conformidade
RO	Organism notificat (nume şi număr de identificare)	Procedură de evaluare a conformității
SK	Notifikovaný orgán (Názov a identifikačné číslo)	Postup posudzovania zhody
SV	Anmält organ (namn och identifikationsnummer)	Förfarande för bedömning av överensstämmelse
TR	Onaylanmış Kuruluş (İsim ve Tanım Numarası)	Uygunluk Değerlendirme Prosedürü

EN	**Quality Management System Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples**
BG	Система за управление на качеството Приложение IX, глави I и III, включително оценка на техническата документация на съответните изделия въз основа на представителни проби
CS	Systém řízení kvality Příloha IX Kapitoly I a III, včetně posouzení technické dokumentace dotčených prostředků na základě reprezentativních vzorků
DA	Kvalitetsstyringssystem Bilag IX kapitel I og III, Herunder en vurdering af den tekniske dokumentation for relevant udstyr på baggrund af repræsentative prøver
DE	Qualitätsmanagementsystem Anhang IX Kapitel I und III, einschließlich einer Bewertung der Technischen Dokumentation für betroffene Produkte auf der Grundlage repräsentativer Stichproben
EL	Σύστημα Διαχείρισης Ποιότητας Παράρτημα IX Κεφάλαια I και III, συμπεριλαμβάνεται αξιολόγηση του τεχνικού φακέλου για προϊόντα που εξετάζονται με βάση αντιπροσωπευτικά δείγματα
ES	Sistema de Gestión de Calidad Anexo IX, capítulos I y III, se incluye una evaluación de la documentación técnica para los productos afectados sobre la base de muestras representativas
ET	Kvaliteedijuhtimissüsteem IX lisa I ja III peatükk Sealhulgas asjaomaste seadmete tehnilise dokumentatsiooni hindamist esindavate valimite põhjal
FR	Système de gestion de la qualité Annexe IX Chapitres I et III, Inclut une évaluation de la documentation technique pour les dispositifs concernés, sur la base d'échantillons représentatifs
HR	Sustav upravljanja kvalitetom Prilog IX., Poglavlja I. i III., uključujući ocjenjivanje tehničke dokumentacije za predmetne proizvode na temelju reprezentativnih uzoraka
HU	Minőségirányítási rendszer IX. melléklet, I. és III. fejezet, ideértve az érintett eszközök műszaki dokumentációjának reprezentatív minták alapján való értékelését
IT	Sistema di gestione della qualità Allegato IX Capitoli I e III, compresa una valutazione della documentazione tecnica per i dispositivi interessati sulla base di campioni rappresentativi
LV	Kvalitātes vadības sistēma IX pielikuma I un III nodaļa, tostarp attiecīgo ierīču tehniskās dokumentācijas novērtējums, pamatojoties uz reprezentatīviem paraugiem
LT	Kokybės valdymo sistema IX priedo I ir III skyriai, įskaitant atitinkamų priemonių techninės dokumentacijos vertinimą remiantis tipiniais pavyzdžiais
NO	Kvalitetsstyringssystem Vedlegg IX kapittel I og III, inkludert en vurdering av den tekniske dokumentasjonen for aktuelt utstyr på grunnlag av representative prøver
PL	System Zarządzania Jakością Załącznik IX, Rozdziały I oraz III, w tym ocena dokumentacji technicznej danych wyrobów na podstawie reprezentatywnych próbek
PT	Sistema de gestão da qualidade Anexo IX Capítulos I e III, Incluindo uma avaliação da documentação técnica para os dispositivos em questão com base em amostras representativas
RO	Sistemul de management al calității Anexa IX, Capitolele I și III inclusiv o evaluare a documentației tehnice pentru dispozitivele în cauză pe baza unor probe reprezentative.
SK	Systém riadenia kvality Príloha IX Kapitoly I a III, vrátane posúdenia technickej dokumentácie príslušných pomôcok na základe reprezentatívnych vzoriek
SV	Kvalitetsledningssystem Bilaga IX Kapitel I och III, Inklusive en bedömning av den tekniska dokumentationen för berörda produkter som grundar sig på representativa urval
TR	Kalite Yönetim Sistemi Ek IX Bölüm I ve III Temsili numuneler bazında ilgili cihazlar için teknik dokümantasyonun değerlendirilmesi dahil

EN	EU Certificate No.	Common Specifications (CS)	Full Name
BG	ЕС Сертификат №	Общи спецификации (ОС)	Пълно наименование
CS	Číslo certifikátu EU	Společné specifikace	Celý název
DA	EU-certifikatnummer	Fælles specifikationer	Fulde navn
DE	Nr. des EU-Zertifikats	Gemeinsame Spezifikationen (GS)	Vollständiger Name
EL	Αριθμός πιστοποιητικού ΕΕ	Κοινές προδιαγραφές (ΚΠ)	Πλήρης ονομασία
ES	Número certificado UE	Especificaciones comunes	Nombre completo
ET	EL-i sertifikaadi nr	Ühtsed kirjeldused	Täisnimi
FR	N° certificat UE	Spécifications communes	Nom complet
HR	EU potvrda br.	Zajedničke specifikacije („CS“)	Puni naziv
HU	EU-tanúsítvány száma	Egységes előírások	Teljes név
IT	N° del certificato UE	Specifiche comuni (SC)	Nome completo
LV	ES sertifikāta Nr.	Kopīgās specifikācijas	Pilns nosaukums
LT	ES sertifikatas Nr.	Bendrosios specifikacijos	Vardas ir pavardė
NO	EU-sertifikatnr.	Felles spesifikasjoner	Fullt navn
PL	Nr Certyfikatu UE	Wspólne specyfikacje	Imię i nazwisko
PT	Certificado UE Nº	Especificações comuns	Nome completo
RO	Nr. certificat UE:	Specificații comune (CS)	Numele complet
SK	Certifikát EÚ č.	Spoločné špecifikácie	Celý názov
SV	Nummer på EU-intyg	Gemensamma specifikationer	Fullständigt namn
TR	AB Sertifika Numarası	Genel Spesifikasyonlar (GS)	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EN	**We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro. Toto prohlášení je v souladu s Přílohou IV nařízení IVD a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5ης Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico *in vitro* descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico *in vitro*. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allakirjutanud, kinnitame, et eespool kirjeldatud *in vitro* diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (*in vitro* diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic *in vitro* indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic *in vitro*. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni *in vitro* dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o *in vitro* dijagnostičkim medicinskim proizvodima. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak czennel kijelentjük, hogy a fent leírt in vitro orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács in vitro diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) *in vitro* sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici *in vitro*. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) *in vitro* diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par *in vitro* diagnostikas medicīniskām ierīcēm. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) *in vitro* diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos priemonių taikytinas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til *in vitro*-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til *in vitro*-diagnostikk. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki in vitro spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki in vitro. Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico *in vitro* descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico *in vitro*. Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnații, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic in vitro descrise mai sus sunt conforme cu dispozițiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul in vitro. Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpísaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotníckych pomôckach in vitro. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för *in vitro*-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för *in vitro*-diagnostik. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen in vitro diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli In Vitro Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0488KF
Basic UDI-DI Name: Cholesterol2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T8820	Cholesterol2	53359	W01010205
04T8830	Cholesterol2	53359	W01010205

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 31 OCT 2024

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature:
Date of Approval: 31 Oct 2024

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 31 OCT 2024
Supersedes: 25-Sep-2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 31 OCT 2024

Abbott

Declaration of Conformity

Certificate Identification: DOC-08P4220-SD DLK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08P4220	53006	Alinity c Creatine Kinase Reagent Kit	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 05 May 2022

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 29-Apr-2022
Date Issued: 05 May 2022
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 31-Dec-2016
Effective (Date or Lot Number): 05-May-2022

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9522** Description: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9522** Descrizione: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
24/11/2017

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9532** Description: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9532** Descrizione: **Alinity c CK-MB Reagent Kit**

EDMA: **11.01.01.14**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
24/11/2017

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9501** Description: **Alinity c CK-MB Calibrator Kit**

EDMA: **11.50.03.02**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:
1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:
1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9501** Descrizione: **Alinity c CK-MB Calibrator Kit**

EDMA: **11.50.03.02**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:
1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:
1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
24/11/2017

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **09P9510** Description: **Alinity c CK-MB Control Kit**

EDMA: **11.50.02.01**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **09P9510** Descrizione: **Alinity c CK-MB Control Kit**

EDMA: **11.50.02.01**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
24/11/2017

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0491K4
Basic UDI-DI Name: Creatinine2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9120	Creatinine2	53251	W01010207

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 10 SEP 2024

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 09-SEP-2024

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford Co. Longford Ireland

Date Issued: 10 SEP 2024
Supersedes: 13-Mar-2023

Place Issued: Lisnamuck, Longford Co. Longford Ireland
Effective (Date or Lot Number): 10 SEP 2024

ABBOTT

Declaration of Conformity

Certificate Identification: 04T96
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T9620	53030	Gamma-Glutamyl Transferase2	**Self-declared**
04T9630	53030	Gamma-Glutamyl Transferase2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Manager Regulatory Affairs**
Date of Approval:	09-SEP-2021	Date of Approval:	09 - Sep - 2021
Date Issued:	09-SEP-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	09 - Sep - 2021

Abbott

Declaration of Conformity

Certificate Identification: DOC-07P5520, 07P5530-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
07P5520	53301	Alinity c Glucose Reagent Kit	**Self-declared**
07P5530	53301	Alinity c Glucose Reagent Kit	

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-Jul-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 13-Oct-2017
Effective (Date or Lot Number): 22-Jul-2021

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACP0775J9
Basic UDI-DI Name: Alinity c Ultra HDL
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
07P7520	Alinity c Ultra HDLReagent Kit	53391	W01010215
07P7530	Alinity c Ultra HDLReagent Kit	53391	W01010215

Manufacturer (Name and Address)	Abbott GmbH, Max-Planck-Ring 2, 65205 Wiesbaden, Germany	
Manufacturer SRN	DE-MF-000009455	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of manufacture) (Name and Address)	Sekisui Diagnostics P.E.I. Inc. 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65, 80339 München, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, including an assessment of the technical documentation for devices concerned on the basis of representative samples.	**EU Certificate No.** **No. V12 010051 0137**
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Claudia Becker
Function: Director Quality Assurance
Signature: C. Becker
Date of Approval: 12 Oct 2023

Full Name: Susanne Ulrich
Function: Assoc. Director Regulatory Affairs
Signature: Susanne Ulrich
Date of Approval: 12/Oct/2023

Signed for, and on behalf of: Abbott GmbH, Wiesbaden, Germany

Date Issued: 12 Oct 2023
Place Issued: 65205 Wiesbaden, Germany

Supersedes: 08-Jul-2022
Effective (Date or Lot Number): 12-Oct-2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0498KJ
Basic UDI-DI Name: Iron2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9820	Iron2	54758	W01010216

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/Site Quality Head
Signature:
Date of Approval: 21 Nov 2023

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 21 Nov 2023

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 21 Nov 2023
Supersedes: 09 December 2021

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 21 Nov 2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0498KJ
Basic UDI-DI Name: Iron2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9820	Iron2	54758	W01010216

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Certification Body, Ridlerstraße 65, 80339 Munich Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/Site Quality Head
Signature:
Date of Approval: 21 Nov 2023

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 21 Nov 2023

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 21 Nov 2023
Supersedes: 09 December 2021

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 21 Nov 2023

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACT0499KL
Basic UDI-DI Name: Lactate Dehydrogenase2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04T9920	Lactate Dehydrogenase2	53072	W01010119
04T9930	Lactate Dehydrogenase2	53072	W01010119

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV Süd Product Service GmbH Zertifizierstellen, Ridlerstraße 65 • 80339 Munich Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: Siobhan Wright
Function: Director Quality Assurance/Site Quality Head
Signature: Siobhan Wright
Date of Approval: 14-DEC-2021

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S Gallagher
Date of Approval: 13-DEC-2021

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 14-DEC-2021
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 14-DEC-2021

SEKISUI DIAGNOSTICS
Because every result matters™

DECLARATION OF CONFORMITY

Manufacturer:	Sekisui Diagnostics P.E.I. Inc 70 Watts Avenue Charlottetown Prince Edward Island C1E 2B9 Canada
European Representative:	MDSS GmbH Schiffgraben 41 30175 Hannover Germany

Product:

Product Code	Name	GMDN Code
07P7120	Alinity c Direct LDL Reagent Kit	53395

Classification: General IVD

Conformity Assessment Route: Annex III, self-certified

We hereby declare that the above-mentioned products meet the provisions of the Council Directive 98/79EC for in vitro diagnostic medical devices. All supporting documents are held by the manufacturer.

Place of Issue: Prince Edward Island, Canada

Signature: _____ 29-Jun-2021

Penny White
Senior Manager Regulatory Affairs
Sekisui Diagnostics PEI Inc.

Date

Sekisui Diagnostics P.E.I. Inc.
70 Watts Avenue
Charlottetown, Prince Edward Island
C1E 2B9 Canada
Tel: 902-566-1396 Fax: 902-628-6504
www.sekisuidiagnostics.com

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACU0400JJ
Basic UDI-DI Name: Lipase2
Risk Class: Class C

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U0020	Lipase2	53108	W01010123
04U0001	Lipase2 Calibrator	53109	W0101050302

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339, Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance
Signature:
Date of Approval: 19 DEC 2024

Full Name: Rosemary McEntire
Function: Manager Regulatory Affairs
Signature: R. McEntire
Date of Approval: 19 Dec 2024

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 19 DEC 2024
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 19 DEC 2024

ABBOTT

Declaration of Conformity

Certificate Identification: 08P19
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08P1925 08P1934	46795	Magnesium	Self-declared

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	20-JAN-2021	Date of Approval:	20 JAN 2021
Date Issued:	20-JAN-2021	Place Issued	AIDD, Longford
Supersedes:	13 July 2020	Effective (Date)	20-JAN-2021

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074ACU0403JQ
Basic UDI-DI Name: Phosphorus2
Risk Class: Class B

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
04U0320	Phosphorus2	59123	W01010307
04U0330	Phosphorus2	59123	W01010307

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland	
Manufacturer SRN	IE-MF-000010070	
Authorized Representative (Name and Address)	N/A	
Authorized Representative SRN	N/A	
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland	
Notified Body (Name and Identification Number)	TÜV Süd Product Service GmbH Certification Body, Ridlerstraße 65 • 80339 Munich, Germany Notified Body Number 0123	
Conformity Assessment Procedure	**Quality Management System** Annex IX Chapters I and III, Including an assessment of the technical documentation for devices concerned on the basis of representative samples	**EU Certificate No.** No. V12 054869 0013
Common Specifications (CS)	N/A	

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices. **This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.**

Full Name: David Spellman
Function: Director Quality Assurance/ Site Quality Head
Signature:
Date of Approval: 17 APR 2023

Full Name: Sandra Gallagher
Function: Manager Regulatory Affairs
Signature: S. Gallagher
Date of Approval: 17-APR-2023

Signed for, and on behalf of: Abbott Ireland Diagnostics Division Lisnamuck, Longford, Co. Longford Ireland

Date Issued: 17 APR 2023
Supersedes: N/A

Place Issued: Lisnamuck, Longford, Co. Longford, Ireland
Effective (Date or Lot Number): 17 APR 2023

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **07P5620** Description: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **07P5620** Descrizione: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Filippo De Luca

Date / Data
30/06/2017

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **07P5601** Description: **Alinity c CRP Vario Wide Range Calibrator Kit**

EDMA: **12.50.03.13**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **07P5601** Descrizione: **Alinity c CRP Vario Wide Range Calibrator Kit**

EDMA: **12.50.03.13**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Filippo De Luca

Date / Data
30/06/2017

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **07P5602** Description: **Alinity c CRP Vario High Sensitivity Calibrator Kit**

EDMA: **12.50.03.13**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:

1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **07P5602** Descrizione: **Alinity c CRP Vario High Sensitivity Calibrator Kit**

EDMA: **12.50.03.13**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:

1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Filippo De Luca

Date / Data
30/06/2017

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

SENTINEL
DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **07P5621** Description: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:
1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:
1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **07P5621** Descrizione: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:
1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:
1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data

12/12/2018

SENTINEL DIAGNOSTICS

Mod. 98 - Rev.4 - Data:03/09/2013

EC DECLARATION OF CONFORMITY

for *in vitro* diagnostic medical device (IVD) - Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy - Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry, immunochemistry, coagulation, molecular biology and rapid tests for immunology and serology" declares, under its own responsibility that the device

REF: **07P5624** Description: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

complies with all the essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (legislative decree nr. 332/2000).

It therefore declares and assures, under its own responsibility, that the device:
1. complies with the applicable provisions of the Directive
2. is not included in the list A and B of Annex II of the Directive
3. is designed, manufactured and placed on the market according to the company certified quality system, in compliance with the current quality regulations as expressed in Annex III of the Directive.

Furthermore, the manufacturer declares to:
1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

DICHIARAZIONE DI CONFORMITA' CE

per dispositivo medico diagnostico *in vitro* (IVD) - Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia - Via Robert Koch 2, fabbricante del dispositivo appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, biologia molecolare e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che il dispositivo

REF: **07P5624** Descrizione: **Alinity c CRP Vario Reagent Kit**

EDMA: **12.11.01.09**

soddisfa i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che il dispositivo:
1. soddisfa le disposizioni applicabili della Direttiva
2. non è incluso nell'elenco A e B dell'Allegato II della Direttiva
3. è progettato, fabbricato e immesso in commercio nell'ambito dell'applicazione di un sistema qualità aziendale dichiarato conforme e certificato secondo le norme vigenti così come descritto dall'Allegato III della Direttiva.

Il fabbricante dichiara inoltre di:
1. conservare e tenere a disposizione dell'Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo di almeno dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel CH. SpA
A Legal Representative
Un Legale Rappresentante
Ugo De Luca

Date / Data
12/12/2019

CE DECLARATION OF CONFORMITY

Manufacturer: *Hersteller* *Fabricante* *Fabricant* *Produttore*	*Fabricante* *Producent* *Tillverkare* *Κατασκευαστής*	**BIOKIT, S.A.** **Av. Can Montcau, 7** **08186 Lliçà d'Amunt** **Barcelona** **Spain**

Biokit hereby declares that the product(s) listed below conform to the European Union directive and standards identified in this declaration.

Biokit erklärt, dass die aufgeführten Produkt(e) mit den Bestimmungen der angegebenen EU-Richtlinien und mit den aufgeführten normativen Dokumenten in Übereinstimmung sind.

Biokit declara por la presente que los producto(s) abajo mencionados, están conformes con las directivas y normas Europeas identificadas en esta declaración.

Biokit déclare par la présente, que le(s) produit(s) sous-mentionné(s), est (sont) conforme(s) aux directives et normes Européennes identifiées dans cette déclaration.

Biokit dichiara con la presente che il(i) prodotto(i) sottomenzionato(i) è(sono) conformi alla direttiva e agli standard specificati in questa dichiarazione.

Biokit declara pelo presente que o(s) produto(s) abaixo mencionado(s) está/estão conforme a Directiva e normas da Comissão Europeia especificadas nesta declaração.

Biokit erklærer herved, at det (de) nedenfor anførte produkt(er) er i overensstemmelse med de EU-direktiver og standarder, der er anført i denne erklæring.

Biokit bekräftar härmed att nedan uppräknade produkt(er) är förenlig(a) med de EU-direktiv och standarder som identifieras i denna deklaration

Η Biokit με το παρόν δηλώνει ότι το προϊόν(–τα) που αναφέρονται κατωτέρω συμμορφώνονται με την οδηγία της Ευρωπαϊκής Ένωσης και τα πρότυπα που παρατίθενται στην παρούσα δήλωση.

EU Directive:
EU-Richtlinie Directiva UE Directive Européenne Direttiva Europea Directiva UE EU-Direktiv EU Direktiv Οδηγία ΕΕ

IVD - 98/79/EC (27/10/1998)

Standard(s):
Normen und Richtlinien Estándar(es) Norme(s) Norma(e) Padrão/Padrões Standard(er) Standard(er) Πρότυπο(-α)

ISO 13485

Notified Body:
Benannte Stelle Organismo Notificado Organisme Notifié Organismo Notificato Organismo Notificado Teknisk Kontrollorgon Anmält Organ Κοινοποιημένος Οργανισμός

Name: ***Other Devices***	Code: ***N/A***

- Certificate Nº: N/A Annex III

Product(s):
Produkt(e) Producto(s) Produit(s) Prodotto(i) Produto(s) Produkt(er) Produkt(er) Προϊόν(-τα)

Product(s) *Produkt(e)* *Producto(s)* *Produit(s* *Prodotto(i)*	*Produto(s)* *Produkt(er)* *Produkt(er)* *Προϊόν(-τα)*
P/N	
01R1622	**Alinity c RF Reagent Kit (400 T)**
01R1632	**Alinity c RF Reagent Kit (920 T)**
01R1601	**Alinity c RF Standard**

August 28th, 2018

Signature
Pau Planas
CEO
Biokit, S.A

Date

ABBOTT

Declaration of Conformity

Certificate Identification: 04T81
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04T8120	53989	Total Protein2	**Self-declared**
04T8130	53989	Total Protein2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	22-OCT-20	Date of Approval:	22 OCT 2020
Date Issued:	22-OCT-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	22-OCT-20

ABBOTT

Declaration of Conformity

Certificate Identification: 04U06
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04U0620	53462	Triglyceride2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Thomas Breslin**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Manager Regulatory Affairs**
Date of Approval:	24-JUN-2021	Date of Approval:	25-JUNE-2021
Date Issued:	24-JUN-2021	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	25-JUNE-2021

ABBOTT

Declaration of Conformity

Certificate Identification:	04U09
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
04U0920	53583	Uric Acid2	**Self-declared**
04U0930	53583	Uric Acid2	**Self-declared**

Authorized European Representative (name and address)	Not Applicable
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name (printed):	**Siobhan Wright**	Full Name (printed):	**Lorraine Whitney**
Position:	**Director Quality Assurance/ Site Quality Head**	Position:	**Director Regulatory Affairs**
Date of Approval:	18-NOV-20	Date of Approval:	18 Nov 2020
Date Issued:	18-NOV-20	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Supersedes:	Not Applicable	Effective Date:	18-NOV-20

Abbott

Declaration of Conformity

Certificate Identification: DOC-08P1620, 08P1630-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08P1620	53590	Alinity c Urea Nitrogen Reagent Kit	**Self-declared**
08P1630	53590	Alinity c Urea Nitrogen Reagent Kit	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Abbott Laboratories, 1921 Hurd Drive, Irving, Texas 75038, USA.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: C. Becker
Full Name: **Claudia Becker**
Position: **Director Quality Assurance**
Date of Approval: 22 Jul 2021

Signature: Tiffini Jenkins
Full Name: **Tiffini Jenkins**
Position: **Manager Regulatory Affairs**
Date of Approval: 11-JUL-2021
Date Issued: 22-Jul-2021
Place Issued: 65205 Wiesbaden, Germany
Supersedes: 05-Jan-2018
Effective (Date or Lot Number): 22-Jul-2021

SENTINEL
DIAGNOSTICS

EC DECLARATION OF CONFORMITY

For *in vitro* diagnostic medical devices (IVD) – Directive 98/79/EC

The undersigned Sentinel CH. SpA, having its premises in Milan, Italy – Via Robert Koch 2, manufacturer of the family of devices named as "kits for clinical chemistry and immunochemistry, coagulation and rapid tests for immunology and serology" declares, under its own responsibility that the below listed devices comply with all essential requirements listed in Annex I of the 98/79/EC Directive, as prescribed in Annex III of such Directive and its Italian transposition (Legislative Decree nr. 322/2000).

It therefore declares and assures, under its own responsibility, that the devices:

1. comply with the applicable provisions of the Directive
2. are not included in the list A and B of Annex II of the Directive
3. are designed, manufactured and placed on the market according to the company certified quality system, in compliance with ISO 9001 and ISO 13485 as per indication expressed in Annex III of the Directive.

DICHIARAZIONE DI CONFORMITÀ CE

per dispositivi medico diagnostici *in vitro* IVD) – Direttiva 98/79/CE

La scrivente Sentinel CH. SpA con sede in Milano, Italia – Via Robert Koch 2, fabbricante dei dispositivi appartenente alla famiglia denominata "kit per chimica clinica, immunochimica, coagulazione, e test rapidi per immunologia e serologia" dichiara sotto la propria responsabilità che i dispositivi sotto elencati soddisfano i requisiti essenziali applicabili richiesti dall'Allegato I della Direttiva 98/79/CE, come prescritto dall'Allegato III della medesima Direttiva e suo recepimento italiano (Decreto Legislativo 332/2000).

A tale scopo garantisce e dichiara sotto la propria responsabilità che i dispositivi:

1. soddisfano le disposizioni applicabili della Direttiva
2. non sono inclusi nell'elenco A e B dell'Allegato III della Direttiva
3. sono progettati, fabbricati ed immessi in commercio nell'ambito dell'applicazione di un sistema di qualità aziendale dichiarato conforme e certificato secondo le norme ISO 9001 e ISO 13485 come descritto dall'Allegato III della Direttiva.

Code/Codice	Product Description/Nome prodotto
6K26-30	CRP Vario
6K26-41	CRP Vario
6K26-10	CRP Calibrator Set
6K26-12	CRP Calibrator WR
6K26-14	CRP Calibrator HS
6K26-21	CRP Control HS
6K89-30	Ammonia Ultra
6K91-30	Ceruloplasmin
4P79-30	UIBC Liquid
8L24-31	Creatinine (Enzymatic)
8L24-41	Creatinine (Enzymatic)
8L25-30	Lithium
6K89-20	Ammonia Controls
6K30-10	Clin Chem Cal
6K31-10	Plasmaproteins Cal 3x
1P93-30	Cystatin C
1P93-10	Cystatin C Calibrator

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com

SENTINEL
DIAGNOSTICS

Code/Codice	Product Description/Nome prodotto
1P93-20	Cystatin C Control Set
6K25-10	CK-MB Calibrator
6K25-20	CK-MB Control
6K30-20	Clin Chem Control 1
6K30-21	Clin Chem Control 2
6K32-20	Immuno Control 1
6K32-21	Immuno Control 2
6K32-22	Immuno Control Set
6K90-20	Bile Acids Controls
6K98-10	Fructosamine Control 1
6K98-20	Fructosamine Control 2
4P80-30	Lambda Light Chains
6K24-30	Cholinesterase
6K25-30	CK-MB
6K22-30	Pancreatic Amylase
6K96-30	Kappa Light Chains
6K23-30	HBDH
6K90-30	Bile Acids
6K92-30	Dibucaine CHE
6K93-30	Copper
6K94-30	Fructosamine
6K95-30	Iron
6K95-41	Iron

Furthermore, the manufacturer declares to:

1. keep and make available for the Competent Authority the product technical file, as specified in Annex III of the 98/79/CE Directive, as well as to retain the batch records for a period of at least ten (10) years after the production date of the last lot
2. have instituted and keep up to date an adequate procedure to guarantee the market surveillance requested by the Directive.

Il fabbricante dichiara inoltre di:

1. conservare e tenere a disposizione delle Autorità Competente il fascicolo tecnico di prodotto, specificato nell'Allegato III della Direttiva 98/79/CE, nonché le registrazioni di produzione e controllo per un periodo almeno di dieci anni dalla data di produzione dell'ultimo lotto
2. avere istituito e di mantenere un'idonea procedura per garantire la sorveglianza post-vendita richiesta dalla Direttiva.

Sentinel Ch. SpA
A Legal Representative
Un Legale Rappresentante
Dr. Filippo De Luca

Date/Data
19/06/2015

SENTINEL CH. SpA - Via Robert Koch, 2 - 20152 MILANO - Tel. +39 02 345514.1 Fax +39 02 345514.64 - Cod. Fisc. e P. IVA / VAT IT 07118040158
Registro delle Imprese di Milano - REA n° 1139796 - Registro AEE n° IT08040000004820 - Cap. Soc. / Nom. Cap. € 2.500.000 i.v. - sentinel@sentinel.it
www.sentineldiagnostics.com