EU DECLARATION OF CONFORMITY

Manufacturer:	**Boditech Med Inc.** 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Republic of Korea (SRN: KR-MF-000011028)
European Representative:	**Obelis s.a.** Bd. Général Wahis, 53, 1030 Brussels, Belgium (SRN: BE-AR-000000106)
Product:	**ichroma™ II** - Catalog No.: FPRR021 - Basic UDI-DI: 880613301004BJ
Intended use:	ichroma™ II is an analyzer intended for use in conjunction with fluorescence immunoassay (FIA) kits for quantitative, semi-quantitative and qualitative measurements of various analytes. For *in vitro* diagnostic use only.
Classification:	Class A (Rule 5) - According to the Annex VIII of the REGULATION (EU) 2017/746
Conformity Assessment Route:	According to the Annex II and Annex III of the REGULATION (EU) 2017/746

We, Boditech Med Inc., herewith declare under our sole responsibility that the above-mentioned product is in conformity with the following European Union harmonisation legislation.

- REGULATION (EU) 2017/746 OF EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE 2011/65/EC OF EUROPEAN of 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

All supporting documentation is retained under the premises of the manufacturer

Standards applied:	EN ISO 13485:2016, EN 13612:2002, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 61010-1:2010, EN 61010-2-101:2017, EN 61326-2-6:2020, EN 62304:2006, EN 62366-1:2015, ISO/TR 20416:2020, IEC 62321:2008
Place, Date of Issue:	Chuncheon, Korea, August 11, 2022
Signature:	Sung Joong Kim / PRRC

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ES atitikties deklaracija

Gamintojas:	Boditech Med Inc. 43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do, 24398, Korėjos Respublika (SRN: KR-MF-000011028)
Atstovas Europoje:	Obelis s.a. Bd. General Wahis, 53, 1030 Brussels, Belgija (SRN: BE-AR-000000106)
Produktas:	ichroma™ II - Katalogo nr.: FPRR021 - Pagrindinis UDI-ID: 880613301004BJ
Paskirtis:	ichroma™ II yra analizatorius, skirtas naudoti kartu su fluorescencinių imunotyrimų (FIA) rinkiniais kiekybiniams, pusiau kiekybiniams ir kokybiniams įvairių analičių matavimams.
Klasifikacija:	A klasė (5 taisyklė) - Pagal (ES) Reglamento 2017/746 VIII priedą
Atitikties įvertinimo būdas:	Pagal (ES) Reglamento 2017/746 II ir III priedus

Mes, Boditech Med Inc., šiuo dokumentu pagal savo atsakomybę skelbiame, kad nurodyti produktai atitinka Europos Sąjungos darniąją teisią.

- 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos (ES) Reglamentas 2017/746 dėl *in vitro* diagnostikos medicinos prietaisų ir panaikinanti Direktyvą 98/79/EB ir Komisijos sprendimą 2010/227/ES.
- 2011 m. birželio 8 d. Europos Parlamento ir Tarybos Direktyva 2011/65/EB dėl tam tikrų pavojingų medžiagų elektrinėje ir elektroninėje įrangoje naudojimo ribojimo.

Visa palaikomoji dokumentacija saugoma gamintojo patalpose.

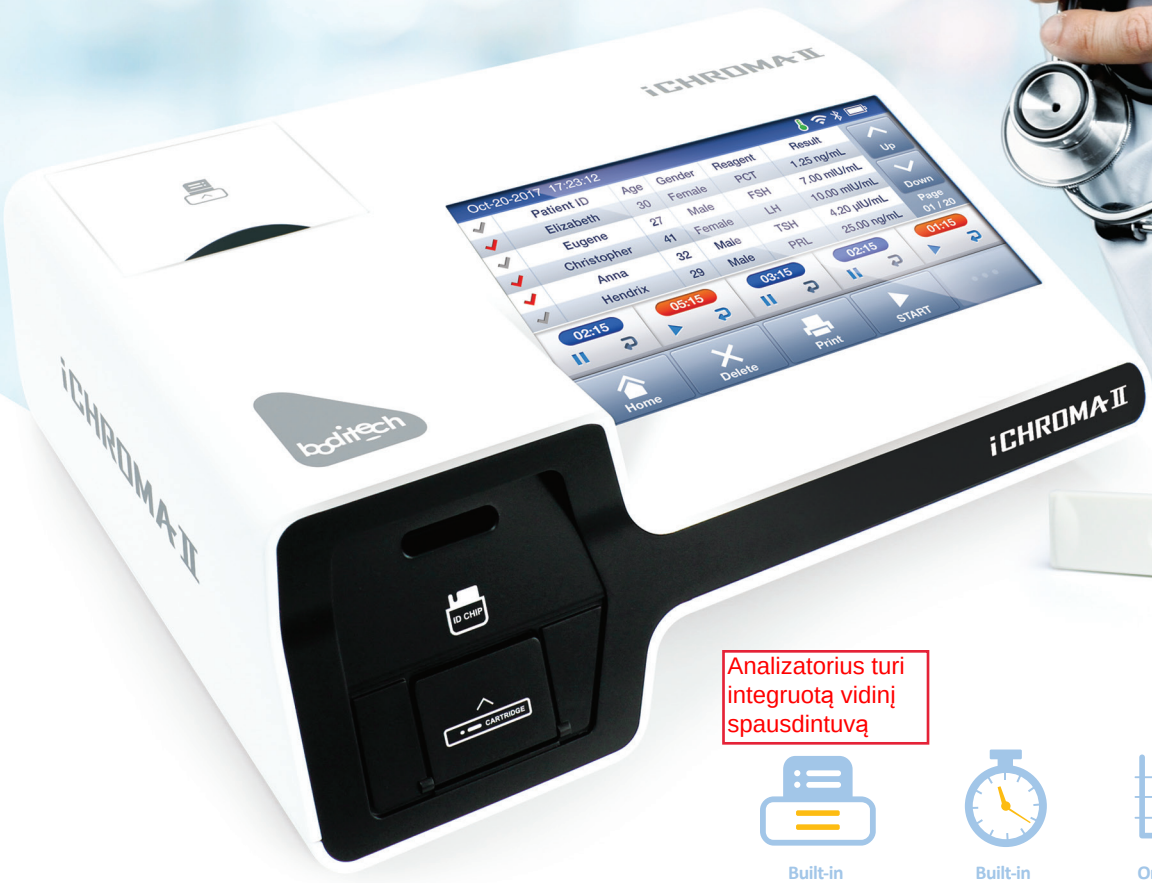
Taikomi standartai:	EN ISO 13485:2016, EN 13612:2002, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 18113-1:2011, EN ISO 18113-3:2011, EN 61010-1:2010, EN 61010-2-101:2017, EN 61326-2-6:2020, EN 62304:2006, EN 62366-1:2015, ISO/TR 20416:2020, IEC 62321:2008
Išleidimo vieta, data:	Chuncheon, Korėja, 2022 m. rugpjūčio 11 d.
Parašas:	*/parašas/* Sung Joong Kim / PRRC

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.
Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.

[redacted] (MB „Beikeris“, įm .k. 304539005)

Advanced compact immuno-analyzer

iCHROMA™ II



Analizatorius turi integruotą vidinį spausdintuvą

Built-in printer

Built-in multi-timers


On-board QC & System check


Battery and AC operated

Reliable Diagnosis of Patients on-the-Spot

2 level calibration

- All items provide 2 level calibrators and Controls
- Boditech Calibrators and Controls

Specifications
276 x 220 x 91 mm
1.3 kgs
100 – 240V AC, 50-60Hz
Internal & external battery

QC / Calibration
System check cartridge
Internal & external controls

Throughput
Up to 30 tests/hour

Interface
7" touch screen
Built-in thermal printer
USB port / Ethernet / SD card slot
LIS/HIS compatible

Memory
1,000 patient results
1,000 QC results
100 User IDs

ichroma™ Parameters

Category	Item	ichroma™	ichroma™ II *ichroma™ III *ichroma™-10	ichroma™-50	ichroma™ M2	*ichroma™ M3	Sample type	Working range
Cardiac	Tn-I	●	●				S/P	0.1-50.0 ng/mL
	Tn-I Plus		●				WB/S/P	0.01-15 ng/mL
	CK-MB	●	●				WB/S/P	3-100 ng/mL
	D-Dimer	●	●				WB/P	50-10,000 ng/mL
	NT-proBNP		●	●			WB/S/P	10-30,000 pg/mL
	Myoglobin	●	●				WB/S/P	5-500 ng/mL
	hsCRP	●	●				WB/S/P	0.1-10.0 mg/L
	Cardiac Triple		●				WB/S/P	TnI 0.01-15 ng/mL CK-MB 3-100 ng/mL Myoglobin 5-500 ng/mL
	ST2		●	●			WB/S/P	3.1-200 ng/mL
Cancer	PSA	●	●				S/P/WB	0.1-100.0 ng/mL (WB:0.5-100.0 ng/mL)
	PSA Plus		●				WB/S/P	0.07-50 ng/mL
	AFP	●	●				WB/S/P	5-350 ng/mL
	AFP Plus		●				WB/S/P	0.5-350 ng/mL
	CEA	●	●				S/P	1-500 ng/mL
	CEA Plus		●				S/P	0.5-200 ng/mL
	iFOB Neo	●	●	●			Feces	25-1,000 ng/mL
Diabetes	HbA1c	●	●				WB	(NGSP) 4-15 %
	Microalbumin	●	●				Urine	2-300 mg/L
	Cystatin C	●	●				S/P	0.1-7.5 mg/L
Hormone	TSH	●	●				S/P	0.1-100.0 μIU/mL
	TSH Plus		●				WB/S/P	0.1-50.0 μIU/mL
	T3	●	●				S/P	0.77-7.70 nmol/L
	T4	●	●				S/P	10.23-300.00 nmol/L
	FSH	●	●				S/P	1-100 mIU/mL
	Progesterone	●	●				S/P	4.45-127.20 nmol/L
	β-HCG	●	●				WB/S/P	5-50,000 mIU/mL
	β-HCG Plus		●				WB/S/P	2-5,000 mIU/mL
	LH	●	●				S/P	1-100 mIU/mL
	PRL	●	●				S/P	1-100 ng/mL
	Testosterone	●	●				S/P	1-10 ng/mL
	Cortisol	●	●				WB/S/P	80-800 nmol/L
	AMH		●				S/P	0.02-10 ng/mL
Infection	CRP	●	●			●	WB/S/P	2.5-300.0 mg/L
	PCT	●	●	●			WB/S/P	0.1-100.0 ng/mL
	PCT Plus		●	●			WB/S/P	0.02-50 ng/mL
	ASO	●	●				S/P	25-800 IU/mL
	HBsAg		●				WB/S/P	0-300 COI
	Anti-HBs		●				WB/S/P	0-500 mIU/mL
	Anti-HCV		●				WB/S/P	0-300 COI
	ROTA		●				Feces	qualitative (0-200 COI)
	NORO		●				Feces	qualitative (0-200 COI)
	Rota/Adeno		●				Feces	qualitative (0-200 COI)
	Dengue IgG/IgM		●				WB/S/P	qualitative (0-200 COI)
	Dengue NS1 Ag		●				WB/S/P	qualitative (0-200 COI)
	Influenza A+B		●	●	●		Nasopharyngeal swab	FluA: 1.4 x 10^3 pfu/mL FluB: 0.5 $TCID_{50}$/mL
	RSV		●	●	●		Nasopharyngeal swab	qualitative
	Influenza A+B/RSV*		●	●	●		Nasopharyngeal swab	FluA: 1.4 x 10^3 pfu/mL FluB: 0.5 $TCID_{50}$/mL RSV:qualitative
	Strep A		●		●		Pharyngeal swab	4 x 10^3 cfu/test
	Adeno*		●				Nasopharyngeal swab/ Nasal aspirate	qualitative
Autoimmune	RF IgM	●	●				WB/S/P	8-200 IU/mL
	Anti-CCP Plus		●				WB/S/P	3.5-300 U/mL
	Total IgE	●	●				WB/S/P	1.00-1,000 IU/mL
Others	Ferritin	●	●				S/P	10-1,000 ng/mL
	Vitamin D	●	●				S/P	8-70 ng/mL
	Calprotectin	●	●	●			Feces	10-1,000 mg/kg
	H.pylori SA	●	●				Feces	qualitative

* Coming soon