

DECLARATION OF CONFORMITY

1) **Manufacturer (Name, department):** Monobind Inc.
Address: 100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES
 and

2) **European authorized representative:** CEpartner4U BV,
Address: ESPOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;
 (on product labels printed as:
 CEpartner4U, ESPOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS Tel: +31 (0)6 516 536 26;
 or as: CEpartner4U, 3951DB, 13, NL tel: +31 (0)6 - 516.536.26)

3) **Product(s) (name, type or model/batch number, etc.):**
 Immunoassay products:
 ELISA,
 CLIA,
 Control,
 Instruments
 (see appendix)

4) **The product(s) described above is in conformity with:**

Document No.	Title	Edition / Date of issue
L 331, 98/79/EC	In-Vitro-Diagnostic Directive	1998-10-27

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

Conformity assessment procedure for CE marking: IVD Directive, Annex III

Lake Forest, USA, 2011-09-27

Tony Shatola; QA Director, Monobind Inc.
(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of manufacturer)*

Maarn, NL: 2011-09-27

Olga Teitlinck; Consultant, CEpartner4U BV
(Place & date of issue (yyyy-mm-dd)) *(name, function and signature of authorized representative)*

Appendix

Date: 2011-09-26

Device types	Item# ELISA	Item# CLIA	Item# Control	Item# Instrument	EDMIS code	Risk Class	Certificate #	First date of CE-marking
Thyroid								
T3 - Triiodothyronine	125-300	175-300			12.04.01.05.00	Low		2005-11-11
T3 - Free Triiodothyronine	1325-300	1375-300			12.04.01.01.00	Low		2005-11-11
T4 - Thyroxine	225-300	275-300			12.04.01.07.00	Low		2005-11-11
T4 - Free Thyroxine	1225-300	1275-300			12.04.01.02.00	Low		2005-11-11
TSH - Thyrotropin	325-300	375-300			12.04.01.11.00	Low		2005-11-11
Rapid TSH - Rapid Thyrotropin	6025-300	6075-300			12.04.01.11.00	Low		2010-06-29
T3U - Triiodothyronine Uptake	525-300	575-300			12.04.01.06.00	Low		2005-11-11
TBG - Thyroxine-Binding Globulin	3525-300	3575-300			12.04.01.09.00	Low		2005-11-11
Tg - Thyroglobulin	2225-300	2275-300			12.04.01.08.00	Low		2005-11-11
T3, T4 & TSH - Triiodothyronine, Thyroxine & Thyrotropin Combo (VAST)	8025-300	8075-300			12.04.01.01.00	Low		2005-11-11
T3 - Triiodothyronine (SBS)	8125-300	8175-300			12.04.01.01.00	Low		2010-06-29
T4 - Thyroxine (SBS)	8225-300	8275-300			12.04.01.01.00	Low		2010-06-29
T3, T4 & TSH - Free Triiodothyronine, Free Thyroxine & Thyrotropin Combo (VAST)	7025-300	7075-300			12.04.01.01.00	Low		2010-06-29
Neonatal Thyroid & Genetics								
NTSH - Neonatal Thyrotropin	3425-300	3475-300			12.04.01.00.00	Low		2005-11-11
NT4 - Neonatal Thyroxine	2625-300	2675-300			12.04.01.12.00	Low		2005-11-11
N 17OHP - Neonatal 17 OH Progesterone	5625-300				12.06.01.07	Low		2008-02-01
Bioidase	8825-300				12.07.02.90.00	Low		2011-09-26
Autoimmune Thyroid								
Anti-Tg - Anti-Thyroglobulin Antigen	1025-300	1075-300			12.10.03.04.00	Low		2005-11-11
Anti-TPO - Anti-Thyropoxidase Antigen	1125-300	1175-300			12.10.03.01.00	Low		2005-11-11
Fertility & Prenatal								
LH - Lutein	625-300	675-300			12.05.01.05.00	Low		2005-11-11
FSH - Follicle	425-300	475-300			12.05.01.04.00	Low		2005-11-11
PRL - Prolactin	725-300	775-300			12.05.01.08.00	Low		2005-11-11
PRL - Prolactin Sequential	6025-300	6075-300			12.05.01.08.00	Low		2005-11-11
hCG - Human Chorionic Gonadotropin	825-300	875-300			12.05.02.05.00	Low		2005-11-11
Rapid hCG - Rapid Human Chorionic Gonadotropin	3325-300				12.05.02.05.00	Low		2005-11-11
FSH, LH, hCG, sPRL Combo (VAST)	8325-300	8375-300			12.05.01.90.00	Low		2006-06-24
AFP, hCG, uE3 Combo (VAST)	8525-300	8575-300			12.05.01.90.00	Low		2010-06-29
Steroid								
Cortisol	3625-300	3675-300			12.06.02.04.00	Low		2005-11-11
DHEA-S - Dehydroepiandrosterone sulfate	5125-300	5175-300			12.05.01.02.00	Low		2010-06-29
DHEA - Dehydroepiandrosterone	7425-300	7475-300			12.05.01.02.00	Low		2011-09-26

Device types	Item# EI/ISA	Item# CLA	Item# Control	Item# Instrument	EDMS code	Risk Class	Certificate #	First date of Certification
E2 – Estradiol	4925-300	4915-300			12.05.01.03.00	Low		2010-06-29
	5025-300	5015-300			12.05.02.02.00	Low		2010-06-29
	4E3 – Estradiol, Unconjugated	4825-300	4815-300		12.05.01.06.00	Low		2010-06-29
	Progesterone	3725-300	3715-300		12.05.01.10.00	Low		2007-11-01
	Testosterone	5325-300	5315-300		12.05.01.10.00	Low		2010-06-29
17OHP – 17 β -hydroxyprogesterone	5225-300	5215-300			12.05.01.07.00	Low		2010-06-29
	17OHP – 17 β -hydroxyprogesterone Ext. Range	9925-300	9915-300		12.05.01.07.00	Low		2010-10-18
Vitamin D3 – 25-hydroxyvitamin D3	7725-300	7715-300			12.05.03.10.00	Low		2011-09-26
Growth & Bone Metabolism								
IGH – Human Growth Hormone	1725-300	1715-300			12.05.04.02.00	Low		2005-11-11
PTH – Parathyroid Hormone	7825-300	7815-300			12.05.03.13.00	Low		2011-09-26
Diabetes								
Insulin	2425-300	2415-300			12.06.01.03.00	Low		2005-11-11
Insulin Rapid	5825-300				12.06.01.03.00	Low		2010-06-29
C-peptide	2725-300	2715-300			12.06.01.01.00	Low		2005-11-11
Insulin & C-peptide Combo (VAST)	7325-300	7315-300			12.06.01.03.00	Low		2005-11-11
Cardiac Markers								
CKMB – Circulating Creatine Kinase (MB)	2925-300	2915-300			12.13.01.02.00	Low		2005-11-11
CTnI – Troponin I	3825-300	3815-300			12.13.01.07.00	Low		2005-11-11
DIG – Digoxin	925-300	915-300			12.08.01.01.00	Low		2005-11-11
HS-CRP – High Sensitivity C-Reactive Protein	3125-300	3115-300			12.13.01.90.00	Low		2005-11-11
Myoglobin	3225-300	3215-300			12.13.01.05.00	Low		2005-11-11
Infectious Diseases								
IGG – AntiH1, Pylori	1425-300	1415-300			15.01.04.03.00	Low		2005-11-11
IGM – AntiH1, Pylori	1525-300	1515-300			15.01.04.03.00	Low		2005-11-11
IGa – AntiH1, Pylori	1625-300	1615-300			15.01.04.03.00	Low		2005-11-11
Cancer Markers								
AFP – Alpha-fetoprotein	1925-300	1915-300			12.03.90.01.00	Low		2005-11-11
CA 125 Ovarian Cancer Antigen	3025-300	3015-300			12.03.01.06.00	Low		2005-11-11
CA 15.3 Breast Cancer Antigen	5625-300	5615-300			12.03.01.02.00	Low		2010-06-29
CA 19.9 – Pancreatic Cancer Antigen	3925-300	3915-300			12.03.01.03.00	Low		2005-11-11
CEA – Carcinoembryonic Antigen	1825-300	1815-300			12.03.01.31.00	Low		2005-11-11
CEA – Carcinoembryonic Antigen Next Generation	4625-300	4615-300			12.03.01.31.00	Low		2010-06-29
fHbCS – Free Beta Human Chorionic Gonadotropin	2025-300	2015-300			12.03.01.90.00	Low		2005-11-11
Allergy & Anemia								
Ferritin	2825-300	2815-300			12.07.01.02.00	Low		2005-11-11
Folate	7525-300	7515-300			12.07.01.03.00	Low		2010-06-29
IGE – Immunoglobulin E	2625-300	2615-300			12.02.01.02.00	Low		2005-11-11
ITR – Transferrin Soluble Receptor	8625-300	8615-300			12.07.01.06.00	Low		2010-06-29
Vitamin B12	7625-300	7615-300			12.07.02.04.00	Low		2011-09-26

Miscellaneous Controls									
Anti-Tg & Anti-TPO – Positive & Negative - Anti-Thyroglobulin, Anti-Thyroperoxidase		Anti-T01			12.50.01.16.00	Low			2010-06-29
High Level Fertility Control – Single Level – Progesterone, Estradiol, Human Chorionic Gonadotropin		FC-300			12.50.01.16.00	Low			2010-06-29
Maternal Control – Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Feta Protein, Estrilol		MC-300			12.50.01.16.00	Low			2010-06-29
Thyroglobulin Control – Tri Level		TG-300			12.50.01.16.00	Low			2010-06-29
H. Pylori IgG Control – Positive & Negative		H-Py- IgG-300			12.50.01.16.00	Low			2010-06-29
Miscellaneous Instruments									
IC hardware + dedicated accessories + software – Autoplex ELISA Analyzer & CLIA Processor				IN006	21.02.10.01	Low			2010-06-29
IC hardware + dedicated accessories + software – Lumax Chemiluminescence Strip Reader				IN001	21.02.10.01	Low			2006-08-24
IC hardware + dedicated accessories + software – Neo-Lumax Chemiluminescence Strip Reader				IN010	21.02.10.01	Low			2011-09-26
IC hardware + dedicated accessories + software – Impulse 2 Chemiluminescence Strip Reader				IN005	21.02.10.01	Low			2006-08-24
IC hardware + dedicated accessories + software – Impulse 3 Chemiluminescence Strip Reader				IN007	21.02.10.01	Low			2010-06-29
IC hardware + dedicated accessories + software – Lumax36 Chemiluminescence Plate Reader				IN004	21.02.10.01	Low			2007-03-01
IC hardware + dedicated accessories + software – Lumilux Chemiluminescence Plate Reader				IN008	21.02.10.01	Low			2011-09-26
IC hardware + dedicated accessories + software – Eldex 3.8 ELISA Strip Reader				IN003	21.02.10.01	Low			2007-09-10
IC hardware + dedicated accessories + software – Neo-Eldex ELISA Strip Reader				IN009	21.02.10.01	Low			2011-09-26
IC hardware + dedicated accessories + software – Microplate Washer				IN002	21.02.10.01	Low			2010-06-29