

**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: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 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:

<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
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

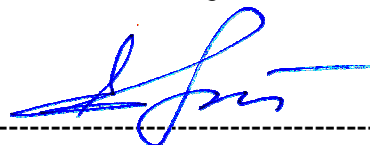


-----  
Tony Shatola; QA Director, Monobind Inc.

(Place & date of issue (yyyy-mm-dd))

(name, function and signature of manufacturer)

Maarn, NL; 2011-09-27



-----  
Olga Teirlinck; Consultant, CEpartner4U BV

(Place & date of issue (yyyy-mm-dd))

(name; function and signature of authorized representative)

## Appendix

Date: 2011-09-26

<i>Device types</i>	<i>Item# ELISA</i>	<i>Item# CLIA</i>	<i>Item# Control</i>	<i>Item# Instrument</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>Certificate #</i>	<i>First date of CE-marking</i>
<b>Thyroid</b>								
T3 – Triiodothyronine	125-300	175-300			12.04.01.05.00	Low		2005-11-11
fT3 – 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
fT4 – 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
fT3, fT4 & TSH – Free Triiodothyronine, Free Thyroxine & Thyrotropin Combo (VAST)	7025-300	7075-300			12.04.01.01.00	Low		2010-06-29
<b>Neonatal Thyroid &amp; Genetics</b>								
NTSH – Neonatal Thyrotropin	3425-300	3475-300			12.04.01.90.00	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	5525-300				12.05.01.07	Low		2008-02-01
Biotinidase	8825-300				12 07 02 90 00	Low		2011-09-26
<b>Autoimmune Thyroid</b>								
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
<b>Fertility &amp; Prenatal</b>								
LH – Lutropin	625-300	675-300			12.05.01.05.00	Low		2005-11-11
FSH – Follitropin	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		2006-08-24
AFP, hCG, uE3 Combo (VAST)	8525-300	8575-300			12.05.01.90.00	Low		2010-06-29
<b>Steroid</b>								
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

<i>Device types</i>	<i>Item# ELISA</i>	<i>Item# CLIA</i>	<i>Item# Control</i>	<i>Item# Instrument</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>Certificate #</i>	<i>First date of CE-marking</i>
E2 – Estradiol	4925-300	4975-300			12.05.01.03.00	Low		2010-06-29
uE3 – Estriol, Unconjugated	5025-300	5075-300			12.05.02.02.00	Low		2010-06-29
Progesterone	4825-300	4875-300			12.05.01.06.00	Low		2010-06-29
Testosterone	3725-300	3775-300			12.05.01.10.00	Low		2007-11-01
Free Testosterone	5325-300	5375-300			12.05.01.10.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone	5225-300	5275-300			12.05.01.07.00	Low		2010-06-29
17OHP - 17-Hydroxyprogesterone Ext. Range	9925-300	9975-300			12.05.01.07.00	Low		2010-10-18
Vitamin D3 – 25-Hydroxyvitamin D3	7725-300	7775-300			12.06.03.10.00	Low		2011-09-26
<b>Growth &amp; Bone Metabolism</b>								
hGH - Human Growth Hormone	1725-300	1775-300			12.06.04.02.00	Low		2005-11-11
PTH - Parathyroid Hormone	7825-300	7875-300			12.06.03.13.00	Low		2011-09-26
<b>Diabetes</b>								
Insulin	2425-300	2475-300			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	2775-300			12.06.01.01.00	Low		2005-11-11
Insulin & C-peptide Combo (VAST)	7325-300	7375-300			12.06.01.03.00	Low		2005-11-11
<b>Cardiac Markers</b>								
CKMB – Circulating Creatine Kinase (MB)	2925-300	2975-300			12.13.01.02.00	Low		2005-11-11
CTnl – Troponin I	3825-300	3875-300			12.13.01.07.00	Low		2005-11-11
DIG – Digoxin	925-300	975-300			12.08.01.01.00	Low		2005-11-11
HS-CRP – High Sensitivity C- Reactive Protein	3125-300	3175-300			12.13.01.90.00	Low		2005-11-11
Myoglobin	3225-300	3275-300			12.13.01.05.00	Low		2005-11-11
<b>Infectious Diseases</b>								
IgG – Anti/H. Pylori	1425-300	1475-300			15.01.04.03.00	Low		2005-11-11
IgM – Anti/H. Pylori	1525-300	1575-300			15.01.04.03.00	Low		2005-11-11
IgA – Anti/H. Pylori	1625-300	1675-300			15.01.04.03.00	Low		2005-11-11
<b>Cancer Markers</b>								
AFP – Alpha-Fetoprotein	1925-300	1975-300			12.03.90.01.00	Low		2005-11-11
CA 125 Ovarian Cancer Antigen	3025-300	3075-300			12.03.01.06.00	Low		2005-11-11
CA 15-3 Breast Cancer Antigen	5625-300	5675-300			12.03.01.02.00	Low		2010-06-29
CA 19-9 - Pancreatic Cancer Antigen	3925-300	3975-300			12.03.01.03.00	Low		2005-11-11
CEA – Carcinoembryonic Antigen	1825-300	1875-300			12.03.01.31.00	Low		2005-11-11
CEA - Carcinoembryonic Antigen Next Generation	4625-300	4675-300			12.03.01.31.00	Low		2010-06-29
fβhCG – Free Beta Human Chorionic Gonadotropin	2025-300	2075-300			12.03.01.90.00	Low		2005-11-11
<b>Allergy &amp; Anemia</b>								
Ferritin	2825-300	2875-300			12.07.01.02.00	Low		2005-11-11
Folate	7525-300	7575-300			12.07.01.03.00	Low		2010-06-29
IgE – Immunoglobulin E	2525-300	2575-300			12.02.01.02.00	Low		2005-11-11
sTfR - Transferrin Soluble Receptor	8625-300	8675-300			12.07.01.06.00	Low		2010-06-29
Vitamin B12	7625-300	7675-300			12.07.02.04.00	Low		2011-09-26

<b>Miscellaneous Controls</b>							
Anti-Tg & Anti-TPO – Positive & Negative - Anti-Thyroglobulin, Anti-Thyroperoxidase			AIT-101		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, Estriol			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			HPy-IgG-300		12.50.01.16.00	Low	2010-06-29
<b>Miscellaneous Instruments</b>							
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 – Lumax96 Chemiluminescence Plate Reader				IN004	21.02.10.01	Low	2007-03-01
IC hardware + dedicated accessories + software – LuMatic 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



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Monobind Inc.**  
**100 North Pointe Drive**  
**Lake Forest, CA 92630**  
**USA**

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

---

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

---

Registration Number: MD19.4585  
Certification Granted: May 18, 2010  
Effective Date: September 25, 2019  
Expiry Date: September 24, 2022





# NSAI

## **Annex to Certificate Number: MD19.4585**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

#### **Activity**

#### **Location**

Headquarters, Administration,  
Design, Manufacturing,  
Distribution

Monobind Inc.  
100 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585

Manufacturing, Distribution

Monobind Inc.  
103 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585/A

**Verified by:  
Operations Manager**