


# 7500 Real-Time PCR Systems Spectral Calibration Kit II

Catalog Number 4351151

Pub. No. 4351155 Rev. B

 **WARNING!** Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from [thermofisher.com/support](http://thermofisher.com/support).

## Contents and storage

Contents	Amount	Storage
Spectral Calibration Plates sealed with optical covers	3	-25°C to -15°C

## Related documentation

For detailed information on instrument setup and the calibration process, refer to the *Applied Biosystems™ 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide* (Pub. no. 4347828).

## Limited product warranty

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# TaqMan™ RNase P Instrument Verification Plate, 96-well

Catalog Number 4310982

Pub. No. 4314333 Rev. H


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## Contents and storage

Contents	Amount	Storage
TaqMan™ RNase P Instrument Verification Plate, 96-well shipped with Optical Compression Pad	1	-25°C to -15°C Do not store in a frost-free freezer.

## RNase P plate layout

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D	NTC	NTC	NTC	NTC	STND 1.25K	STND 1.25K	STND 1.25K	STND 1.25K	STND 2.5K	STND 2.5K	STND 2.5K	STND 2.5K
E	STND 5K	STND 5K	STND 5K	STND 5K	STND 10K	STND 10K	STND 10K	STND 10K	STND 20K	STND 20K	STND 20K	STND 20K
F												
G												
H												

 Unknown 5K

 Unknown 10K

## Related documentation

For detailed information on the plate set-up and analysis procedures, refer to the appropriate Sequence Detection System user guide.

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[thermofisher.com](http://thermofisher.com)


1 December 2015

**ThermoFisher**  
S C I E N T I F I C

# 7500 Real-Time PCR Systems Spectral Calibration Kit I

Catalog Number 4349180

Pub. No. 4350071 Rev. D

 **WARNING!** Read the Safety Data Sheets (SDSs) and follow the handling instructions. Wear appropriate protective eyewear, clothing, and gloves. Safety Data Sheets (SDSs) are available from [thermofisher.com/support](http://thermofisher.com/support).

## Contents and storage

Contents	Amount	Storage
Background Plate sealed with an optical cover	1	-25°C to -15°C
Spectral Calibration Plates sealed with optical covers	7	
Region of Interest (ROI) Calibration Plate sealed with an optical cover	1	

## Related Documentation

For detailed information on instrument setup and the calibration process, refer to the *Applied Biosystems™ 7300/7500/7500 Fast Real-Time PCR System Installation and Maintenance Guide* (Pub. no. 4347828).

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**For Research Use Only. Not for use in diagnostic procedures.**

**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. [www.cepartner4u.com](http://www.cepartner4u.com))

3) Product(s) (name, type or model/batch number, etc.):

Immunoassay products;

**AccuBind® ELISA,**

**AccuLite® CLIA,**

**QSure® Control,**

**Instruments**

*see appendix*

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

<u>Document No.</u>	<u>Title</u>
98/79/EC	<i>In vitro</i> Diagnostic Medical Devices Directive

5) Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2021-09-20

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



Tony Shatola; QA Director, Monobind Inc.  
(name, function and signature of manufacturer)

## Appendix

Date: 2021-09-20

### List of devices.

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
<b>Allergy &amp; Anemia</b>							
Ferritin Test System	2825-300A 2825-300B	2875-300A 2875-300B			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300A 7525-300B	7575-300A 7575-300B			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300A 2525-300B	2575-300A 2575-300B			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300A 8625-300B	8675-300A 8675-300B			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (Vit B12) Test System	7625-300A 7625-300B	7675-300A 7675-300B			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (Anemia Panel VAST) Test System	7825-300A 7825-300B	7875-300A 7875-300B			12.07.01.00.00	Low	2013-09-16
<b>Autoimmune</b>							
Anti-Cyclic Citrullinated Peptide IgG (Anti-CCP IgG) Test System	12725-300A 12725-300B	12775-300A 12775-300B			12.11.01.90.00	Low	2019-04-03
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300A 1025-300B	1075-300A 1075-300B			12.10.03.04.00	Low	2005-11-11
Anti-Thyropoxidase (Anti-TPO) Test System	1125-300A 1125-300B	1175-300A 1175-300B			12.10.03.01.00	Low	2005-11-11
<b>Bone Metabolism &amp; Growth</b>							
Calcitonin Test System	9325-300A 9325-300B	9375-300A 9375-300B			12.06.03.02.00	Low	2019-04-03
Growth Hormone (hGH) Test System	1725-300A 1725-300B	1775-300A 1775-300B			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9025-300A 9025-300B	9075-300A 9075-300B			12.06.03.13.00	Low	2011-09-26
Parathyroid Hormone (PTH) 3rd & 2nd Gen (VAST) Test System	10025-300A 10025-300B	10075-300A 10075-300B			12.06.03.13.00	Low	2019-04-03
25(OH) Vitamin D Total Direct (Vit D-Direct) Test System	7725-300A 7725-300B	7775-300A 7775-300B			12.06.03.10.00	Low	2017-07-05
<b>Cancer Markers</b>							
Alpha-Fetoprotein (AFP) Test System	1925-300A 1925-300B	1975-300A 1975-300B			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300A 3025-300B	3075-300A 3075-300B			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300A 5625-300B	5675-300A 5675-300B			12.03.01.02.00	Low	2010-06-29
CA 19-9 Test System	3925-300A 3925-300B	3975-300A 3975-300B			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300A 1825-300B	1875-300A 1875-300B			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen	4625-300A	4675-300A			12.03.01.31.00	Low	2010-06-29

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
(CEA-Next Gen) Test System	4625-300B	4675-300B					
Free β-Subunit Human Chorionic Gonadotropin (Free Beta hCG) Test System	2025-300A 2025-300B	2075-300A 2075-300B			12.03.01.90.00	Low	2005-11-11
<b>Cardiac Markers</b>							
CK-MB Test System	2925-300A 2925-300B	2975-300A 2975-300B			12.13.01.02.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300A 925-300B	975-300A 975-300B			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300A 3125-300B	3175-300A 3175-300B			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300A 3225-300B	3275-300A 3275-300B			12.13.01.05.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300A 3825-300B	3875-300A 3875-300B			12.13.01.07.00	Low	2005-11-11
<b>Diabetes</b>							
C-Peptide Test System	2725-300A 2725-300B	2775-300A 2775-300B			12.06.01.01.00	Low	2005-11-11
Insulin Test System	2425-300A 2425-300B	2475-300A 2475-300B			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300A 5825-300B				12.06.01.03.00	Low	2010-06-29
Insulin - C-Peptide (Diabetes Panel VAST)	7325-300A 7325-300B	7375-300A 7375-300B			12.06.01.03.00	Low	2005-11-11
<b>Endocrine</b>							
ACTH Test System	10625-300	10675-300			12.06.04.01.00	Low	2019-04-03
Aldosterone Test System	10125-300	10175-300			12.06.02.01.00	Low	2019-04-03
Leptin Test System	10925-300	10975-300			12.06.90.17.00	Low	2019-04-03
<b>Fertility &amp; Prenatal</b>							
Anti-Müllerian Hormone (AMH) Test System	9725-300A 9725-300B	9775-300A 9775-300B			12.05.02.16.00	Low	2019-04-03
Folicle Stimulating Hormone (FSH) Test System	425-300A 425-300B	475-300A 475-300B			12.05.01.04.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300A 825-300B	875-300A 875-300B			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (hCG-XR) Test System	8825-300A 8825-300B	8875-300A 8875-300B			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid hCG) Test System	3325-300A 3325-300B				12.05.02.05.00	Low	2005-11-11
Inhibin A Test System	9525-300A 9525-300B	9575-300A 9575-300B			12.05.01.90.00	Low	2019-04-03
Inhibin B Test System	9625-300A 9625-300B	9675-300A 9675-300B			12.05.01.90.00	Low	2019-04-03
Luteinizing Hormone (LH) Test System	625-300A 625-300B	675-300A 675-300B			12.05.01.05.00	Low	2005-11-11
Pregnancy Associated Plasma Protein – A Mass Units (PAPP-A Mass Units) Test System	12625-300A 12625-300B	12675-300A 12675-300B			12.05.02.10.00	Low	2017-07-05
Prolactin Hormone (PRL) Test System	725-300A 725-300B	775-300A 775-300B			12.05.01.08.00	Low	2005-11-11

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
Prolactin Hormone Sequential (PRLs) Test System	4425-300A 4425-300B	4475-300A 4475-300B			12.05.01.08.00	Low	2005-11-11
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) (Fertility Panel VAST) Test System	8325-300B 8325-300D 8325-300E	8375-300B 8375-300D 8375-300E			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (Triple Screen Panel VAST) Test System	8525-300A 8525-300B	8575-300A 8575-300B			12.05.01.90.00	Low	2010-06-29
<b>Infectious Diseases</b>							
Anti-H. Pylori IgG (H. Pylori Ab IgG) Test System	1425-300A 1425-300B	1475-300A 1475-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM (H. Pylori Ab IgM) Test System	1525-300A 1525-300B	1575-300A 1575-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA (H. Pylori Ab IgA) Test System	1625-300A 1625-300B	1675-300A 1675-300B			15.01.04.03.00	Low	2005-11-11
Anti-SARS-CoV-2 (COVID-19) IgG Test System	11925-300A 11925-300B	11975-300A 11975-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgM Test System	11725-300A 11725-300B	11775-300A 11775-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgA Test System	11825-300A 11825-300B	11875-300A 11875-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System	12025-300A 12025-300B	12075-300A 12075-300B			15.04.80.90.00	Low	2021-09-20
D-Dimer Test System	9225-300A 9225-300B	9275-300A 9275-300B			13.02.05.03.00	Low	2020-08-25
Procalcitonin (PCT) Test System	1425-300A 1425-300B	1475-300A 1475-300B			12.06.90.16.00	Low	2017-07-05
<b>Neonatal</b>							
Neonatal 17OHP (N-17OHP) Test System	5525-300A 5525-300B				12.05.01.07.00	Low	2008-02-01
Neonatal (N-T4) Thyroxine Test System	2625-300A 2625-300B				12.04.01.12.00	Low	2005-11-11
Neonatal TBG (N-TBG) Test System	8925-300A 8925-300B				12.04.01.09.00	Low	2013-09-16
Neonatal TSH (N-TSH) Test System	3425-300A 3425-300B 3425-300D 3425-300E				12.04.01.90.00	Low	2005-11-11
<b>Steroid</b>							
Androstenedione (ANST) Test System	12425-300A 12425-300B	12475-300A 12475-300B			12.05.01.01.00	Low	2021-09-20
Cortisol Test System	3625-300A 3625-300B	3675-300A 3675-300B			12.06.02.04.00	Low	2005-11-11
Dehydroepiandrosterone (DHEA) Test System	7425-300A 7425-300B	7475-300A 7475-300B			12.05.01.02.00	Low	2011-09-26
Dehydroepiandrosterone Sulfate (DHEA-S) Test System	5125-300A 5125-300B	5175-300A 5175-300B			12.05.01.02.00	Low	2010-06-29
Estrone (E1) Test System	10325-300A 10325-300B	10375-300A 10375-300B			12.05.02.04.00	Low	2019-04-03



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Estradiol (E2) Test System	4925-300A 4925-300B	4975-300A 4975-300B			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300A 5025-300B	5075-300A 5075-300B			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300A 4825-300B	4875-300A 4875-300B			12.05.01.06.00	Low	2010-06-29
17-OH Progesterone (17-OHP) Test System	5225-300A 5225-300B	5275-300A 5275-300B			12.05.01.07.00	Low	2010-06-29
17-OH Progesterone SI (17-OHP-SI) Test System	9925-300A 9925-300B	9975-300A 9975-300B			12.05.01.07.00	Low	2010-10-18
Sex Hormone Binding Globulin (SHBG) Test System	9125-300A 9125-300B	9175-300A 9175-300B			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300A 3725-300B	3775-300A 3775-300B			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300A 5325-300B	5375-300A 5375-300B			12.05.01.10.00	Low	2010-06-29
<b>Thyroid</b>							
Total Triiodothyronine (tT3) Test System	125-300A 125-300B 125-300D 125-300E	175-300A 175-300B 175-300D 175-300E			12.04.01.05.00	Low	2005-11-11
Free Triiodothyronine (fT3) Test System	1325-300A 1325-300B 1325-300A 1325-300B	1375-300A 1375-300B 1375-300D 1375-300E			12.04.01.01.00	Low	2005-11-11
Total Triiodothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Triiodothyronine (Rapid -tT3) Test System	11225-300A 11225-300B				12.04.01.01.00	Low	2017-07-05
T3-Uptake (T3U) Test System	525-300A 525-300B	575-300A 575-300B			12.04.01.06.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300A 225-300B 225-300D 225-300E	275-300A 275-300B 275-300D 275-300E			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300A 1225-300B 1225-300D 1225-300E	1275-300A 1275-300B 1275-300D 1275-300E			12.04.01.02.00	Low	2005-11-11
Total Thyroxine (tT4 SBS) Test System	8225-300A 8225-300B	8275-300A 8275-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Thyroxine (Rapid -tT4) Test System	11125-300A 11125-300B				12.04.01.01.00	Low	2017-07-05
Thyrotropin (TSH) Test System	325-300A 325-300B 325-300D 325-300E	375-300A 375-300B 375-300D 375-300E			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300A 6025-300B	6075-300A 6075-300B			12.04.01.11.00	Low	2010-06-29
Thyroxine-Binding Globulin (TBG) Test System	3525-300A 3525-300B	3575-300A 3575-300B			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300A	2275-300A			12.04.01.08.00	Low	2005-11-11

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triiodothyronine (tT3) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E			12.04.01.01.00	Low	2005-11-11
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E			12.04.01.01.00	Low	2010-06-29

<b>Miscellaneous Controls</b>							
Anti-H. Pylori Control (IgA, IgG, IgM) – Positive & Negative			HPC-300		12.50.01.16.00	Low	2013-09-16
Anti-Tg & Anti-TPO Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level			MC-300		12.50.01.16.00	Low	2010-06-29
TBG Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Tg Control – Tri-Level			TG-300		12.50.01.16.00	Low	2010-06-29
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level			TMC-300		12.50.01.16.00	Low	2013-09-16

<b>Miscellaneous Instruments</b>							
Autoplex® ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex® G2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Autoplex® G3 ELISA & CLIA Analyzer				IN006-3	21.02.10.01	Low	2017-07-05
NeoEldex® ELISA Analyzer				IN009	21.02.10.01	Low	2011-09-26
Impulse® 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
NeoLumax® CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26
LuMatic® CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
PrisMatic® ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
PlateWash - Immunoassay Washer				IN002	21.02.10.01	Low	2010-06-29
TITIN® ELISA & CLIA Analyzer				IN015-EC	21.02.10.01	Low	2017-07-05
TITIN® ELISA Analyzer				IN015-E	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA & CLIA Analyzer				IN016-EC	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA Analyzer				IN016-E	21.02.10.01	Low	2017-07-05



# NSAI

## Certificate of Registration of Quality Management System to ISO 13485:2016

**Brazil** - RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009

**Canada** - Medical Devices Regulations – Part 1- SOR 98/282

**United States**- 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D,

21 CFR 820 - Quality System Regulation,

The National Standards Authority of Ireland is an MDSAP Recognized Auditing Organization and certifies that:

**Monobind Inc.**

**100 North Pointe Drive**

**Lake Forest, CA 92630**

**USA**

**Facility ID: F002818**

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

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

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MP19.4585)**

Approved by:  
Kevin Mullaney  
Director of Certification

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Certificate Number: MP19.4585 / Rev 2  
Certification Granted: 2019/09/25  
Effective Date: 2022/09/25  
Expiry Date: 2025/09/24



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National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

National Standards Authority of Ireland, 20 Trafalgar Square, Nashua, New Hampshire, NH 03063, USA T +1 603 882 4412

All valid certifications are listed on NSAI's website - [www.nsaiinc.com](http://www.nsaiinc.com) The continued validity of this certificate may be verified under "Approved Client Listing"



# NSAI

## **Annex to Certificate Number: MP19.4585 / Rev 2**

### **Scope of Registration:**

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

### **Activity**

Headquarters, Design,  
Manufacture

Manufacture, Distribution

### **Location**

Monobind Inc.  
100 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MP19.4585  
Facility ID: F002818

Monobind Inc.  
103 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MP19.4585/A  
Facility ID: F002818

**Verified by:  
Director of Certification**



Dia.Pro  
**Diagnostic**  
Bio**Probes**

# EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HBs Ag one Version ULTRA</b> CODES: <b>SAG1ULTRA.CE (192 tests)</b> SAG1ULTRA.CE.96 (96 tests) SAG1ULTRA.CE.480 (480 tests) SAG1ULTRA.CE.960 (960 tests) SAG1ULTRA.CE.DB (192 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST A
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>DESIGN CERTIFICATE N° 2008 12 0588 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – DECEMBER 2008
<b>PLACE &amp; DATE OF CURRENT EMISSION</b>	SESTO SAN GIOVANNI (MI) – MARCH 2018
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 03/2018



Dia.Pro  
**Diagnostic**  
Bio**Probes**

# EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HCV Ab</b> CODES: <b>CVAB.CE (192 tests)</b> CVAB.CE.96 (96 tests) CVAB.CE.480 (480 tests) CVAB.CE.960 (960 tests) CVAB.CE.DB (192 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST A
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• DESIGN CERTIFICATE N° 2003 12 0392 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – JANUARY 2004
<b>PLACE &amp; DATE OF CURRENT EMISSION</b>	SESTO SAN GIOVANNI (MI) – MARCH 2018
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES s.r.l.

Rev: 0318

## **DECLARATION OF CONFORMITY**

### **PRODUCT IDENTIFICATION**

<b>Product name</b>	<b>Catalogue number</b>
RPR Carbon kit	044150A 044500A

### **MANUFACTURER**

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

### **MEANS OF CONFORMITY**

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.



Eddy Velthuis  
Technical Director