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Letter of Authorization

We, **"Dia.Pro Diagnostic Bioprobes S.r.l."** located at Via G. Carducci, Nr. 27 – **Sesto San Giovanni (Milan) 20099, Italy**, authorize

GLOBAL BIOMARKETING GROUP – MOLDOVA SRL
Str. Tighina 65, Oficiu 607
MD-2001 CHISINAU
REP. MOLDOVA

as our exclusive distributor for the territory of the Republic of Moldova, to participate in various tenders with **Dia.Pro** ELISA products.

We, Dia.Pro Diagnostic Bioprobes S.r.l shall supply our distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL with all products in strict compliance with the existing "Distribution Agreement" rev.0117 valid until 31-Dec-2020, with possibility of renewal upon agreement between both parties for an additional period.

Dia.Pro Diagnostic Bioprobes S.r.l will grant the supply of all awarded tenders until their natural expiry, of which a documental proof has to be provided to Dia.Pro by the distributor GLOBAL BIOMARKETING GROUP – MOLDOVA SRL.

Sincerely yours,

Date: **Milan, 31-January-2018**

Dia.Pro Diagnostic Bioprobes S.r.l.

DIA.PRO. DIAGNOSTIC BIOPROBES S.r.l.

Dr.ssa Fiorenza Scozzesi
Legal Representative

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBs Ab** CODE: **SAB.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2003 12 0390 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev: 05/2018

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EC DECLARATION OF CONFORMITY

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2003 12 0392 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MARCH 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES srl SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. CBG-MLD Nr.4 IDNO 1003600117582 REPUBLICA MOLDOVA MUN. CHIȘINĂU

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HCV IgM** CODE: **CVM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2007 09 0532 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – SEPTEMBER 2007
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MARCH 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HDV Ab** CODE: **DAB.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2003 12 0393 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES srl SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. IGBG-MLD NrA IDNO 1003600117562 REPUBLICA MOLDOVA MUN.

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HDV IgM** CODE: **DIM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2003 12 0395 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBc Ab** CODE: **BCAB.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2003 12 0391 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

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

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBc IgM** CODE: **BCM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2004 03 0424 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

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MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HSV1 IgG** CODE: **HSV1G.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.

PLACE & DATE OF FIRST ISSUE	MILANO – OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO. DIAGNOSTIC BIOPROBES srl

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HSV2 IgG** CODE: **HSV2G.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.

PLACE & DATE OF FIRST ISSUE	MILANO – OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HSV1 IgM** CODE: **HSV1M.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.

PLACE & DATE OF FIRST ISSUE	MILANO – OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES S.r.l.

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HSV2 IgM** CODE: **HSV2M.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE(S)	UNI CEI EN ISO 9001–Nr 50 100 5931/A UNI CEI EN ISO 13485–Nr 50 100 5931/B RELEASED BY CERTIFICATION BODY TÜV Italia S.r.l.

PLACE & DATE OF FIRST ISSUE	MILANO – OCTOBER 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**CMV IgG** CODE: **CMVG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES S.R.L.

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**CMV IgM** CODE: **CMVM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES

Rev: 12/2013

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**Chlamydia Trachomatis IgG** CODE: **CTG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev:	05/2018

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**Chlamydia Trachomatis IgM** CODE: **CTM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**TOXO IgG** CODE: **TOXOG.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev: 12/2013

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**TOXO IgM** CODE: **TOXOM.CE** (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	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.

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318 • UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HP IgG** CODE: **HPG.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – MARCH 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev: 05/2018

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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HP IgM** CODE: **HPM.CE** (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)

PLACE & DATE OF FIRST ISSUE	MILANO – APRIL 2004
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

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EC DECLARATION OF CONFORMITY

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

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	• 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 • DESIGN CERTIFICATE N° 2008 12 0588 ED RELEASED BY EC NOTIFIED BODY N° 0318 • UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – DECEMBER 2008
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MARCH 2018
SIGNATURE **Legal Representative** **Dr.ssa Fiorenza Scozzesi**	

Rev: 03/2018

Monobind Inc.
The World Resource for Diagnostic Products

www.monobind.com

100 North Pointe Drive
Lake Forest, CA 92630

TEL 949.951.2665
FAX 949.951.3539

Orange County, California, January 10, 2020

IM Global Biomarketing Group - Moldova SRL,
Tighina str.65,office 607
MD-2001,Chisinau, Republic of Moldova

Commercialization Agreement

To Whom It May Concern:

We, Monobind Inc., an ISO 13485 certified company specializing in the research, development and manufacturing of in vitro diagnostic products for clinical and research application, located at 100 North Pointe Drive, Lake Forest, California 92630 USA;

Hereby authorizes and entitles IM Global Biomarketing Group from Moldova legally registered at Tighina str.65,office 607 MD-2001,Chisinau to effect clinical trials and evaluation of goods, registration of the goods at Health Ministry of Moldova, receive certificate of registration and conclude an agreement on consulting and examination of the documents needed for the registration in Moldova.

This is also to confirm that IM Global Biomarketing Group is the exclusive distributor our AccuBind® ELISA and AccuLite® CLIA products and accessories in Moldova. IM Global Biomarketing Group is authorized to promote and supply our products, to contract for their delivery and take part in tenders with our products.

This authorization is valid until January 1, 2021.

On behalf of the Monobind Inc.

MONOBIND, INC. INCORPORATED NOV. 20 1978 CALIFORNIA

Alicia Jerome Volkov
Marketing Director
Monobind Inc.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GBG-MLD" Nr.4 IDNO 1003600117582 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

Monobind Inc.
ISO 13485 Certified Company

NSAI

Quality System Approval Certificate
In Vitro Diagnostic Medical Devices Directive 98/79/EC

*The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (In Vitro Diagnostics Medical Devices) Regulations (S.I. No. 304 of 2001)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Monobind Inc.

100 North Pointe Drive
Lake Forest
CA 92630
USA

For the Product Family

Total and Free Prostate Specific Antigen (PSA and Free PSA) IVD, kit, chemiluminescent immunoassay (CLIA) and enzyme immunoassay (ELISA) and control

GMDN Code: 54664, 54669

On the basis of examination under the requirements of Annex IV, Section 3 of Directive 98/79/EC, The use of the NSAI Notified Body identification number **0050** in conjunction with CE Marking of Conformance for this product is hereby authorized.

Registration Number:	**304.1006**
Original Registration:	**28 October 2011**
Last Amended on:	**10 July 2018**
Remains valid until:	**27 October 2022**

Signed:

Approved by:
Geraldine Larkin
Chief Executive Officer, NSAI

Approved by:
Susan Murphy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.

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.eu)

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:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

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; 2013-09-16

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

A Shatola

Tony Shatola; QA Director, Monobind Inc.

(name; function and signature of manufacturer)

Maarn, NL; 2013-09-16

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

Olga Teirlinck; Consultant, CEpartner4U BV

(name; function and signature of authorized representative)

Appendix

Date: 2013-09-16

List of devices.

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Thyroid							
Total Triidothyronine (tT3) Test System	125-300	175-300			12.04.01.05.00	Low	2005-11-11
Free Triidothyronine (fT3) Test Stystem	1325-300	1375-300			12.04.01.01.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300	275-300			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300	1275-300			12.04.01.02.00	Low	2005-11-11
Thyrotropin (TSH) Test System	325-300	375-300			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300	6075-300			12.04.01.11.00	Low	2010-06-29
T3-Uptake (T3U) Test System	525-300	575-300			12.04.01.06.00	Low	2005-11-11
Thyroxine-Binding Globulin (TBG) Test System	3525-300	3575-300			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300	2275-300			12.04.01.08.00	Low	2005-11-11
Total Thyroxine (tT4), Total Triidothyronine (tT3) & Thyroid Stimulating Hormone (TSH) Thyroid Panel (VAST) Test System	8025-300	8075-300			12.04.01.01.00	Low	2005-11-11
Total Triidothyronine (tT3 SBS) Test System	8125-300	8175-300			12.04.01.01.00	Low	2010-06-29
Total Thyroxine (tT4 SBS) Test System	8225-300	8275-300			12.04.01.01.00	Low	2010-06-29
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone Free Thyroid Panel (VAST) Test System	7025-300	7075-300			12.04.01.01.00	Low	2010-06-29
Neonatal Thyroid & Genetics							
Neonatal TSH (N-TSH) Test System	3425-300	3475-300			12.04.01.90.00	Low	2005-11-11
Neonatal (N-T4) Thyroxine Test System	2625-300	2675-300			12.04.01.12.00	Low	2005-11-11
Neonatal 17OHP (N-17OHP) Test System	5525-300	5575-300			12.05.01.07	Low	2008-02-01
Neonatal TBG (N-TBG) Test System	8925-300	8975-300			12.04.01.09.00	Low	2013-09-16
Autolmmune Thyroid							
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300	1075-300			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300	1175-300			12.10.03.01.00	Low	2005-11-11
Fertility & Prenatal							
Luteinizing Hormone (LH) Test System	625-300	675-300			12.05.01.05.00	Low	2005-11-11
Follicle Stimulating Hormone (FSH) Test System	425-300	475-300			12.05.01.04.00	Low	2005-11-11
Prolactin Hormone (PRL) Test System	725-300	775-300			12.05.01.08.00	Low	2005-11-11
Prolactin Hormone Sequential (PRLs) Test System	6025-300	6075-300			12.05.01.08.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300	875-300			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (Ext. Range hCG) Test System	8825-300	8875-300			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid	3325-300				12.05.02.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
-hCG) Test System							
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) Fertility Panel (VAST) Test System	8325-300	8375-300			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (VAST) Test System	8525-300	8575-300			12.05.01.90.00	Low	2010-06-29
Pregnancy Associated Plasma Protein - A (PAPP-A) Test System	7925-300	7975-300			12.05.02.10.00	Low	2013-09-16
Steroid							
Cortisol Test System	3625-300	3675-300			12.06.02.04.00	Low	2005-11-11
DHEA-S Test System	5125-300	5175-300			12.05.01.02.00	Low	2010-06-29
Dehydroepiandrosterone (DHEA) Test System	7425-300	7475-300			12.05.01.02.00	Low	2011-09-26
Estradiol (E2) Test System	4925-300	4975-300			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300	5075-300			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300	4875-300			12.05.01.06.00	Low	2010-06-29
Sex Hormone Binding Globulin (SHBG) Test System	9125-300	9175-300			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300	3775-300			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300	5375-300			12.05.01.10.00	Low	2010-06-29
17α-OH Progesterone Test System	5225-300	5275-300			12.05.01.07.00	Low	2010-06-29
17α-OH Progesterone - SI Test System	9925-300	9975-300			12.05.01.07.00	Low	2010-10-18
Growth & Bone Metabolism							
Growth Hormone (hGH) Test System	1725-300	1775-300			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9225-300	9275-300			12.06.03.13.00	Low	2011-09-26
25-Hydroxyvitamin D3 (Vitamin D3) Test System	7725-300	7775-300			12.06.03.10.00	Low	2011-09-26
Diabetes							
Insulin Test System	2425-300	2475-300			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300				12.06.01.03.00	Low	2010-06-29
C-Peptide Test System	2725-300	2775-300			12.06.01.01.00	Low	2005-11-11
Insulin - C-Peptide (VAST)	7325-300	7375-300			12.06.01.03.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300	2975-300			12.13.01.02.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300	3875-300			12.13.01.07.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300	975-300			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300	3175-300			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300	3275-300			12.13.01.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Infectious Diseases							
Anti-H. Pylori IgG Test System	1425-300	1475-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM Test System	1525-300	1575-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA Test System	1625-300	1675-300			15.01.04.03.00	Low	2005-11-11
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300	1975-300			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300	3075-300			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300	5675-300			12.03.01.02.00	Low	2010-06-29
CA -19-9 Test System	3925-300	3975-300			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300	1875-300			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen (CEA) Test System	4625-300	4675-300			12.03.01.31.00	Low	2010-06-29
Free β-Subunit Human Chorionic Gonadotropin (fβhCG) Test System	2025-300	2075-300			12.03.01.90.00	Low	2005-11-11
Allergy & Anemia							
Ferritin Test System	2825-300	2875-300			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300	7575-300			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300	2575-300			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300	8675-300			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (B12) Test System	7625-300	7675-300			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (VAST) Test System	7825-300	7875-300			12.07.01.00.00	Low	2013-09-16
Miscellaneous Controls							
Anti-Thyroglobulin (Anti-Tg), Anti-Thyroperoxidase (Anti-TPO) Control – Positive & Negative			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 (Tg) 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
H. Pylori IgM Control – Positive & Negative			HPy-IgM-300		12.50.01.16.00	Low	2013-09-16
H. Pylori IgA Control – Positive & Negative			HPy-IgA-300		12.50.01.16.00	Low	2013-09-16
Thyroid Binding Globulin (TBG) Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Miscellaneous Instruments							
Autoplex ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex Generation 2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Lumax CLIA Analyzer				IN001	21.02.10.01	Low	2008-08-24
Neo-Lumax CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Impulse 2 CLIA Analyzer				IN005	21.02.10.01	Low	2006-08-24
Impulse 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
Lumax96 CLIA Analyzer				IN004	21.02.10.01	Low	2007-03-01
LuMatic CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
Eldex 3.8 ELISA Analyzer				IN003	21.02.10.01	Low	2007-09-10
Neo-Eldex ELISA Analzyer				IN009	21.02.10.01	Low	2011-09-26
PrisMAtic ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
Plate Washer Microplate Washer				IN002	21.02.10.01	Low	2010-06-29

NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2012

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 Reagent Products and Equipment

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:
Susan Murphy
European Medical Device
Operations Manager

Registration Number: MD19.4585
Certification Granted: May 18, 2010
Effective Date: Oct 29, 2017
Expiry Date: Oct 28, 2020

NSAI

Annex to Certificate Number: MD19.4585

Scope of Registration:

The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays, and Related Reagent Products and Equipment

Activity	Location
Headquarters, Design, Manufacture	Monobind Inc. 100 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585
Manufacture, Design	Monobind Inc. 103 North Pointe Drive Lake Forest, CA 92630 USA File No.: MD19.4585/A

Verified by:
Operations Manager

NovaTec Immundiagnostica GmbH

NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany
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E-Mail: info@NovaTec-ID.com
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GBG-MDL SRL
Global Biomarketing Group
Moldova
65 Tighina Str., office 607
MD-2001 Chisinau
Republic of Moldova

November 18th, 2019

To whomever it may concern:

By hereby, we, **NovaTec Immundiagnostica GmbH**, Waldstraße 23 A6, 63128 Dietzenbach, Germany, declare that **GBG-MDL SRL** Global Biomarketing Group Moldova, 65 Tighina Str., office 607, MD-2001 Chisinau, Republic of Moldova is our authorized distributor designated by us to promote, to register, to distribute and to represent our products in the territory of the Republic of Moldova.

This declaration is valid until December 31th, 2020 unless terminated by either party before the date of expiration.

With best regards

NovaTec Immundiagnostica GmbH

Britta-Maria Duchmann Berlie
General Manager

NOVATEC IMMUNDIAGNOSTICA GmbH
Waldstraße 23 A6
63128 Dietzenbach, Germany

NovaTec Immundiagnostica GmbH

Product List – CE Marked

Certified by

ISO 13485:2016

EC – Directive 98 / 79 EC
For In-Vitro-Diagnostics

2019-10

28102019-BZ

NovaTec Immundiagnostica GmbH

NovaLisa® Virology

Prod. No.	Name
ADVA0010	Adenovirus IgA
ADVG0010	Adenovirus IgG
ADVM0010	Adenovirus IgM
CHIG0590	Chikungunya Virus IgG capture
CHIM0590	Chikungunya Virus IgM µ-capture
CMVG0110	Cytomegalovirus (CMV) IgG
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
CMVM0110	Cytomegalovirus (CMV) IgM
DENG0120	Dengue Virus IgG
DENM0120	Dengue Virus IgM
DVM0640	Dengue Virus IgM µ-capture
EBVA0150	Epstein-Barr Virus (VCA) IgA
EBVG0150	Epstein-Barr Virus (VCA) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
EBVM0150	Epstein-Barr Virus (VCA) IgM
EBVG0580	Epstein-Barr Virus (EBNA) IgG
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSVG0250	Herpes simplex Virus 1+2 (HSV) IgG
HSVM0250	Herpes simplex Virus 1+2 (HSV) IgM
HSV1G0500	Herpes simples Virus 1 (HSV-1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV-2) IgM
INFA0290	Influenza Virus A IgA
INFG0290	Influenza Virus A IgG
INFM0290	Influenza Virus A IgM
INFA0300	Influenza Virus B IgA
INFG0300	Influenza Virus B IgG
INFM0300	Influenza Virus B IgM
MEAG0330	Measles Virus IgG
AMEA7330	Avidity Measles Virus IgG
MEAM0330	Measles Virus IgM
MUMG0340	Mumps Virus IgG
MUMM0340	Mumps Virus IgM
PAIA0360	Parainfluenza Virus 1,2,3 IgA
PAIG0360	Parainfluenza Virus 1,2,3 IgG
PARG0370	Parvovirus B 19 IgG
PARM0370	Parvovirus B 19 IgM
RSVA0380	Respiratory syncytial Virus IgA
RSVG0380	Respiratory syncytial Virus IgG
RSVM0380	Respiratory syncytial Virus IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG

28102019-BZ

RUBM0400	Rubella Virus IgM µ-capture
TICG0440	TBE / FSME IgG
TICM0440	TBE / FSME IgM
PTICG044	TBE / FSME IgG plus
VZVA0490	Varicella-Zoster Virus (VZV) IgA
VZVG0490	Varicella-Zoster Virus (VZV) IgG
VZVM0490	Varicella-Zoster Virus (VZV) IgM
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa® Bacteriology

Prod. No.	Name
BAR0900	Bartonella
BOPA0030	Bordetella pertussis IgA
BOPG0030	Bordetella pertussis IgG
BOPM0030	Bordetella pertussis IgM
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
BRUG0050	Brucella IgG
BRUM0050	Brucella IgM
CHLA0070	Chlamydia trachomatis IgA
CHLG0070	Chlamydia trachomatis IgG
CHLM0070	Chlamydia trachomatis IgM
CHLA0510	Chlamydia pneumoniae IgA
CHLG0510	Chlamydia pneumoniae IgG
CHLM0510	Chlamydia pneumoniae IgM
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
COX1G0600	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	Coxiella burnetii (Q-Fever) Phase 2 IgM
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
LEGG0650	Legionella Pneumophila IgG
LEGM0650	Legionella Pneumophila IgM
LEPG0660	Leptospira IgG
LEPM0660	Leptospira IgM
MYCA0350	Mycoplasma pneumoniae IgA

NovaTec Immundiagnostica GmbH

MYCG0350	Mycoplasma pneumoniae IgG
MYCM0350	Mycoplasma pneumoniae IgM
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus

NovaLisa® Parasites

Prod. No.	Name
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
TOXA0460	Toxoplasma gondii IgA
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TOXM0460	Toxoplasma gondii IgM µ-capture

NovaLisa® Worms

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
ECHG0130	Echinococcus IgG
FIL0760	Filariasis
SCHG0410	Schistosoma mansoni IgG
SCHM0410	Schistosoma mansoni IgM
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa® Fungi

Prod. No.	Name
ASPG0680	Aspergillus fumigatus IgG
ASPM0680	Aspergillus fumigatus IgM
CANA0060	Candida albicans IgA
CANG0060	Candida albicans IgG
CANM0060	Candida albicans IgM

28102019-BZ

NovaLisa ® Hormones

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
FT41050	Free T4
TSH1030	TSH

Hormones

STEROID HORMONES
(ELISAs for the determination of steroid hormones in plasma and serum)

Prod. No.	Name
DNOV001	Cortisol
DNOV002	Testosterone
DNOV003	17 beta-Estradiol
DNOV004	17-OH Progesterone
DNOV005	DHEA-S
DNOV006	Progesterone
DNOV007	Free Estriol
DNOV008	Androstenedione
DNOV009	Free Testosterone
DNOV011	Total Estriol
DNOV012	Aldosterone

STEROID HORMONES IN URINE
(ELISAs for the determination of steroid hormones in urine)

Prod. No.	Name
DNOV010	Urinary Cortisol

STEROID HORMONES IN SALIVA
(ELISAs for the determination of steroid hormones in saliva)

Prod. No.	Name
DSNOV20	Cortisol Saliva
DSNOV21	Testosterone Saliva
DSNOV22	17 beta-Estradiol Saliva
DSNOV24	DHEA-S Saliva
DSNOV25	Progesterone Saliva
DSNOV26	Estriol Saliva
DSNOV27	Androstenedione Saliva

NovaTec Immundiagnostica GmbH

PROTEIN HORMONES
(ELISAs for the determination of proteins in plasma and serum)

Prod. No.	Name
DNOV030	LH
DNOV031	FSH
DNOV032	Prolactin
DNOV033	AFP
DNOV034	beta HCG

THYROID HORMONES
(ELISAs for the determination of thyroid hormones and antibodies)

Prod. No.	Name
DNOV051	Free T3
DNOV053	Total T3
DNOV054	Total T4
DNOV057	Thyroglobulin

DIABETES MONITORING
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV111	Insulin
DNOV112	C-Peptide

CIRCULATING IMMUNO COMPLEXES
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV093	CIC-C1q
DNOV094	CIC-C3d
DNOV096	CH-50

TUMOR MARKERS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV 060	CEA
DNOV061	CA 125
DNOV062	CA 15-3
DNOV063	CA 19-9

NovaTec Immundiagnostica GmbH

MISCELLANEOUS
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
DNOV100	Ferritin
DNOV101	HGH
DNOV102	IgE

NovaLisa® Autoimmune

Autoimmune
(ELISAs for the determination of specific autoimmune antibodies)

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO

Rheumatology
(ELISAs for the determination of specific analytes in plasma and serum)

Prod. No.	Name
RFM3010	Rheumatoid Factor IgM

NovaLisa® Recombinant Antigens

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
HANG0670	Hantavirus IgG
HANM0670	Hantavirus IgM
HELA0220	Helicobacter pylori IgA
PHELA022	Helicobacter pylori IgA plus
HEVG0780	Hepatitis E Virus (HEV) IgG
HEVM0780	Hepatitis E Virus (HEV) IgM
HSV1G0500	Herpes simples Virus 1 (HSV-1) IgG
HSV1M0500	Herpes simplex Virus 1 (HSV-1) IgM
HSV2G0540	Herpes simplex Virus 2 (HSV-2) IgG
HSV2M0540	Herpes simplex Virus 2 (HSV-2) IgM
MAL0620	Malaria
STRO0690	Strongyloides
ZVG0790	Zika Virus IgG capture
ZVM0790	Zika Virus IgM µ-capture

NovaTec Immundiagnostica GmbH

NovaLisa® Quantitative Assays (WHO standardized)

Prod. No.	Name
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebycterium diphtheriae toxin 5S IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani toxin 5S IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaLisa® Quantitative Assays

Prod. No.	Name
ATG1010	Anti-TG
ATPO1020	Anti-TPO
BPTA0610	Bordetella pertussis toxin (PT) IgA
BPTG0610	Bordetella pertussis toxin (PT) IgG
CORG0090	Corynebacterium diphtheriae toxin IgG
CORG5009	Corynebacterium diphtheriae toxin 5S IgG
PCORG009	Corynebacterium diphtheriae toxin 5S IgG plus
FT41050	Free T4
HELA0220	Helicobacter pylori IgA
HELG0220	Helicobacter pylori IgG
PHELA022	Helicobacter pylori IgA plus
PHELG022	Helicobacter pylori IgG plus
RFM3010	Rheumatoid Factor IgM
RUBG0400	Rubella Virus IgG
ARUB7400	Avidity Rubella Virus IgG
TETG0430	Clostridium tetani toxin IgG
TETG5043	Clostridium tetani 5S toxin IgG
PTETG043	Clostridium tetani toxin 5S IgG plus
TICG0440	TBE / FSME IgG
PTICG044	TBE / FSME IgG plus
TOXG0460	Toxoplasma gondii IgG
ATOX7460	Avidity Toxoplasma gondii IgG
TSH1030	TSH

NovaTec
Immundiagnostica GmbH

NovaLisa® IgM µ-capture Assays

Prod. No.	Name
CHIM0590	Chikungunya Virus IgM µ-capture
DVM0640	Dengue Virus IgM µ-capture
RUBM0400	Rubella Virus IgM µ-capture
TOXM0460	Toxoplasma gondii IgM µ-capture
ZVM0790	Zika Virus IgM µ-capture

NovaLisa® Antibody Assays

Prod. No.	Name
ASCG0020	Ascaris lumbricoides IgG
CHAG0560	Chagas (Trypanosoma cruzi) IgG
TRYP0570	Chagas
ENTG0140	Entamoeba histolytica IgG
LEIG0310	Leishmania infantum IgG
MAL0620	Malaria
STRO0690	Strongyloides
TAEG0420	Taenia solium IgG
TOCG0450	Toxocara canis IgG
TRIG0480	Trichinella spiralis IgG

NovaLisa® Avidity Assays

Prod. No.	Name
ACMV7110	Avidity Cytomegalovirus (CMV) IgG
AEBV7150	Avidity Epstein-Barr Virus (VCA) IgG
AMEA7330	Avidity Measles Virus IgG
ARUB7400	Avidity Rubella Virus IgG
ATOX7460	Avidity Toxoplasma gondii IgG

NovaLisa® Liquor Diagnostic

Prod. No.	Name
BORG0040	Borrelia burgdorferi IgG
BORM0040	Borrelia burgdorferi IgM

28102019-BZ

DRG
INTERNATIONAL
INC.

To: Agentia Medicamentului si Dispozitivelor Medicale

We, DRG International, Inc., having a registered office located at 841 Mountain Avenue, Springfield, New Jersey 07081, USA, assign "GBG-MLD"SRL, having a registered office at Str. Tighina 65, Chisinau MD -2001, Moldova, as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC and 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices in the territory of the Republic of Moldova.

Place: Springfield, New Jersey, USA Date: 9 January 2020

Signed: _____

Eric Van Bladel
Chief Operating Officer

DRG INTERNATIONAL, INC. Springfield, New Jersey 07081 USA

SOCIETATEA CU RASPUNDERE LIMITATA "GBG-MLD" S.R.L. IDNO 1003600 REPUBLICA MOLDOVA, MUN. CHISINAU

841 MOUNTAIN AVENUE
SPRINGFIELD, NEW JERSEY 07081 USA (973) 564-7555
E-MAIL: corp@drg-international.com FAX: (973) 564-7556 WEBSITE: www.drg-international.com

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

DRG International., Inc.
841 Mountain Avenue
Springfield NJ 07081
USA

has established and applies a quality management system for medical devices for the following scope:

Manufacturing and distribution of in-vitro diagnostic reagents used in the diagnosis of autoimmune status, cancer, cardiac markers, disease status, fertility testing, pregnancy testing, diabetes and immune status

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-02-21
Certificate Registration No.:	SX 60126687 0001
An audit was performed, Report No.:	21238159 003
This Certificate is valid until:	2020-11-22

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-02-21

Dipl -Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de tuv com http //www tuv com/safety

Liofilchem®

Microbiology products since 1983

Roseto degli Abruzzi, 11 January 2020

Authorization Letter

To whom it may concern

We, **LIOFILCHEM S.R.L.**, manufacturer of diagnostics for microbiology, certified ISO 9001 and ISO 13485, located in Via Scozia, Zona Industriale, 64026 Roseto degli Abruzzi (TE) Italy

do hereby authorize the company

GBG-MLD SRL
65 Tighina Str. Office 607
MD-2001, Chisinau
Moldova

to distribute our following products in **Moldova** (below defined as "the Territory"):

The medical devices manufactured by Liofilchem comply with the European Union directive 98/79/EC for in vitro diagnostic devices (IVD).
A Quality Agreement is attached to this letter as Annex 1.

This authorization is valid to 31.12.2022 and is not automatically renewed.

The cooperation between **GBG-MLD SRL** and **Liofilchem** can be terminated by either Party before 31.12.2022 through a 30 day written notice.

In faith,

Fabio Brocco
COO
Liofilchem

Liofilchem s.r.l.
Via Scozia - Zona Industriale
64026, Roseto degli Abruzzi (TE) Italy
Tel +39 0858930745
Fax +39 0858930330

Capitale Sociale € 825.600 i.v.
R.E.A. Teramo n. 79331
Reg. Soc. Tribunale di Teramo 4124
P.I. e C.F. 00530130673
www.liofilchem.com

TÜV SÜD Italia

CERTIFICATO

Nr 50 100 11497 - Rev. 02

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)

SEDE OPERATIVA:
OPERATIONAL SITE:

CONTRADA PIANE VOMANO 2 - TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine (IAF 12, 29)

***Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination** (IAF 12, 29)*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A SSI N° 055G ISP N° 057E
SGA N° 016D ITX N° 001L LAB N° 0076
SCR N° 009F SGE N° 013M PRD N° 081B
EMAS N° 013P PRS N° 077C

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Management Service

Validità / *Validity*

Dal / From 2017-10-24

Al / To 2020-10-23

Data emissione / *Printing Date* 2017-10-24

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* **2012-09-25**

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATO

N° Q5 17 09 71067 004

Titolare del certificato:

Liofilchem S.r.l.
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

Stabilimento(i):

Liofilchem S.r.l.
Via Scozia,64026 Roseto degli Abruzzi (TE), ITALIA

Liofilchem S.r.l.
Contrada Piane Vomano,Traversa di Via Grecia,
64026 Roseto degli Abruzzi (TE), ITALIA

Marchio di certificazione:

Campo di applicazione:

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro

Norma(e) applicata(e):

EN ISO 13485:2016
Dispositivi medici – Sistemi di gestione per la qualità - Requisiti per scopi regolamentari
(ISO 13485:2016)
DIN EN ISO 13485:2016

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Vedere anche note sul retro.

N° del rapporto: ITA956016

Valido da: 2017-12-09
Valido fino al: 2020-12-08

Data, 2017-12-01

Stefan Preiß

Pagina 1 di 1
Traduzione per scopi informativi. La sola versione inglese (tedesca) è legalmente impegnativa.

TÜV SÜD Italia

CERTIFICATO

Nr 50 100 11497 - Rev. 02

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)

SEDE OPERATIVA:
OPERATIONAL SITE:

CONTRADA PIANE VOMANO 2 - TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine (IAF 12, 29)

***Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination** (IAF 12, 29)*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A SSI N° 055G ISP N° 057E
SGA N° 016D ITX N° 001L LAB N° 0076
SCR N° 009F SGE N° 013M PRD N° 081B
EMAS N° 013P PRS N° 077C

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Management Service

Validità / *Validity*
Dal / From 2017-10-24
Al / To 2020-10-23

Data emissione / *Printing Date*
2017-10-24

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

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

CERTIFICATO

N° Q5 071067 0006 Rev. 00

Titolare del certificato: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

Stabilimento(i): Liofilchem S.r.l.
Via Scozia,64026 Roseto degli Abruzzi (TE), ITALIA

Liofilchem S.r.l.
Contrada Piane Vomano,Traversa di Via Grecia,
64026 Roseto degli Abruzzi (TE), ITALIA

Marchio di certificazione:

Campo di applicazione: **Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro**

Norma(e) applicata(e): EN ISO 13485:2016
Dispositivi medici – Sistemi di gestione per la qualità - Requisiti per scopi regolamentari
(ISO 13485:2016)
DIN EN ISO 13485:2016

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Vedere anche note sul retro.

N° del rapporto: ITA1070742

Valido da: 2018-12-19
Valido fino al: 2021-12-18

Data, 2018-12-19

Stefan Preiß

Traduzione per scopi informativi. La sola versione inglese (tedesca) è legalmente impegnativa.

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 071067 0006 Rev. 00

Holder of Certificate: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

Facility(ies): Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), ITALY

Certification Mark:

Scope of Certificate: **Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA1070742

Valid from: 2018-12-19
Valid until: 2021-12-18

Date. 2018-12-19

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ВЕКТОР БЕСТ

АО "Вектор-Бест"
630117, г Новосибирск, а/я 492
тел.: (383) 227-73-60, 332-36-34
тел./факс: 332-67-49, 332-67-52
e-mail: vbmarket@vector-best.ru
internet: http://www.vector-best.ru

ОГРН 1025404347550
ИНН 5433104584/ КПП 543301001
р/с 40702810244020101090
в Сибирском банке ПАО Сбербанк,
БИК 045004641
корр. сч. 30101810500000000641
ОКВЭД 21.20.2, 72.11 / ОКПО 23548172

от 18.11.2019 № КС-151

«GBG-MLD» SRL
Республики Молдова, г. Кишинев,
ул. Тигина,65, оф.607
Чайковскому Т.К.

Авторизация от производителя

Акционерное общество «Вектор-Бест» (Российская Федерация, 630559, Новосибирская область, рабочий поселок, Кольцово, Научно-производственная зона, корпус 36, к. 211) официально удостоверяет, что «GBG-MLD» SRL (Республика Молдова, г. Кишинев, ул. Тигина, 65, оф. 607) имеет право участвовать от имени АО «Вектор-Бест» в тендерах, проводимых медицинскими учреждениями Республики Молдова и осуществлять рекламно-информационное сопровождение.
Срок действия авторизации по 31 декабря 2020 года включительно.

Коммерческий директор АО «Вектор-Бест» _____ Гусев Ю.М.

Акционерное общество Вектор Бест ОГРН 1025401347550 Новосибирская область, р.п. Кольцово

SOCIETATEA CU RĂSPUNDERE LIMITATĂ GBG-MLD SRL IDNO 1003600117582 REPUBLICA MOLDOVA MUN. CHIȘINĂU

Сертификат

mdc medical device certification GmbH
удостоверяет, что на предприятии

ВЕКТОР БЕСТ

АО «Вектор-Бест»
630559, Новосибирская область, р.п. Кольцово,
Научно-производственная зона, корпус 36, к. 211,
Российская Федерация

с производственными площадками согласно приложению к Сертификату

применительно к областям

проектирование и разработка, производство и реализация медицинских изделий in-vitro диагностики (ПЦР, ИФА, биохимия)

была введена и применяется

СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ

Проведенная проверка системы управления качеством показала, что данная система соответствует требованиям стандарта:

EN ISO 13485

Изделия медицинские – Системы менеджмента качества – Регулирующие системные требования

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Дата выдачи	2018-07-13
Срок действия до	2020-07-03
Регистрационный №	D1213100017
Отчет №	P18-00489-117996
Штутгарт, Германия	2018-07-13

Руководитель сертификационного органа

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10

Приложение к Сертификату

№ D1213100017 от 2018-07-13 Стр. 1 из 1

Месторасположение	Область действия
АО «Вектор-Бест», ул. Арбузова, 1/1, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство и реализация медицинских изделий in vitro диагностики
АО «Вектор-Бест», 630559, Новосибирская область, р.п. Кольцово, Научно-производственная зона, корпус 36, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики
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EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2012 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2012+AC:2012 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2013 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641 2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971 2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

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Date: 2017/10/16

Murat Khusainov
General Director AO Vector-Best

Valid until: 2022/07/03

EC DECLARATION OF CONFORMITY

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2-4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products: Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure: Annex III (not including section 6).

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Date: 2013/04/12

Murat Khusainov
General Director ZAO «Vector-Best»

No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep TTV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectoHSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectoHSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectoHHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectoHHV-6 - IgG	ELISA kit for determination of IgG to human herpes virus type 6	D-2166
17.	Ureaplasma urealyticum – IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum – IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis – IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

		antigens	
24.	Ascarid-IgG-EIA-BEST	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lamblia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lamblia antibodies	D-3552
26.	Lamblia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lamblia antibodies	D-3554
27.	Lamblia-antigen-EIA-BEST	ELISA kit for determination of Lamblia antigen	D-3556
28.	Helicobacter pylori-CagA-antigen-EIA-BEST	ELISA kit for determination of total antibodies to CagA Helicobacter pylori	D-3752
29.	TSH-EIA-BEST	ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST	ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST	ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST	ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST	ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST	ELISA kit for determination of IgA to Mycoplasma hominis	D-4358
36.	Mycoplasma pneumoniae-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST	ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectocrimean – CHF – IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectocrimean – CHF – IgM	ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST	ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST	ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST	ELISA kit for determination of concentration of CA 19-9	T-8470
44	CA 15-3-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45	NSE-EIA-BEST	ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST	ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST	ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST	ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST	ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST	ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST	ELISA kit for determination of concentration of Interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST	ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST	ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST	ELISA kit for determination of concentration of Interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST	ELISA kit for determination of concentration of Interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST	ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST	ELISA kit for determination of concentration of N-terminal prohormone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106

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