

AUTHORISATION LETTER

Wr. Neudorf, 07-12-2017

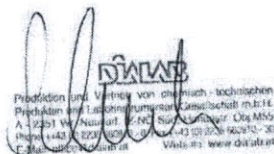
TO WHOM IT MAY CONCERN

We, DIALAB, headquarter in Austria, IZ-NÖ Süd, Hondastrasse Obj. M55, A-2351 Wr. Neudorf hereby declare that the below mentioned company is authorized to sell and distributor our products in the territory of Moldavia:

ECHIPAMED PLUS SRL
Valea Trandafirilor str., 24B, of.80,
MD-2001 Chisinau, Moldova

This certificate remains in force from 01.01.2018 until 31.12.2018 or is terminated during that period on the expiry of not less than 30 days' notice in writing given by either party to the other.

Signed for and on behalf of
DIALAB GES.M.B.H.
IZ NÖ Süd, Hondastrasse,
Objekt M55
A-2351 Wr. Neudorf
AUSTRIA



Christina Schneider
Export Manager



Certificate

mdc medical device certification GmbH
certifies that

**Dialab Produktion und Vertrieb von
chemisch- technischen Produkten und
Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55
2351 Wr. Neudorf
Austria**

for the scope

**production and distribution of reagents and reagent products for in-vitro diagnosis
as well as distribution of instruments for in-vitro diagnosis including accessories**

has introduced and applies a

Quality Management System

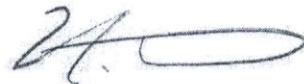
The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

**Medical devices – Quality management systems –
Requirements for regulatory purposes**

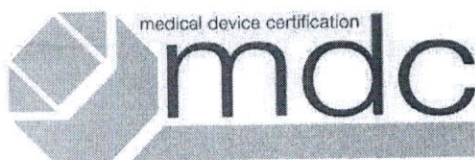
EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

| | |
|------------------|-----------------|
| Valid from | 2016-04-13 |
| Valid until | 2019-04-12 |
| Registration no. | D1419000001 |
| Report no. | P16-00378-68897 |
| Stuttgart | 2016-04-13 |



Head of Certification Body

mdc medical device certification GmbH
Kriegerstraße 6 . 70191 Stuttgart



EC DECLARATION OF CONFORMITY

We



Dialab Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55
2351 Wr. Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed addendum "Devices other than those covered by Annex II (Rapid Tests), Rev.10 (3 pages)", classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Rapid Tests)

meet the applicable provisions of the European Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on Conformity Assessment Procedures according to Annex III of the aforesaid Directive.

This Declaration is valid until 2019-04-12.

Wr. Neudorf, 2017-09-28




DIALAB
Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
A - 2351 Wr. Neudorf, IZ-NOE Sued, Hondastr. Objekt M55
Phone: +43 (0) 2236 660910 | Fax: +43 (0) 2236 660910
E-Mail: office@dialab.at | Website: www.dialab.at

DI Marlene Ramsey
Managing Director

Addendum to the Declaration of Conformity of Devices other than those covered by Annex II (Rapid Tests)

| | | |
|--------------------------------|----------|-------------------------------|
| DIAQUICK Multi-6/3 Drug Panel | Z08930CE | - 30 Panels (30x REF Z08930B) |
| DIAQUICK Multi-6/4 Drug Panel | Z08940CE | - 30 Panels (30x REF Z08940B) |
| DIAQUICK Multi-6/6 Drug Panel | Z13960CE | - 30 Panels (30x REF Z13960B) |
| DIAQUICK Multi-6/7 Drug Panel | Z09970CE | - 30 Panels (30x REF Z09970B) |
| DIAQUICK Multi-6/10 Drug Panel | Z11911CE | - 30 Panels (30x REF Z11911B) |
| DIAQUICK Multi-7 Drug Panel | Z12730CE | - 30 Panels (30x REF Z12730B) |
| DIAQUICK Multi-10 Drug Panel | Z06230CE | - 30 Panels (30x REF Z04230B) |
| | Z04231CE | - 10 Panels (10x REF Z04230B) |
| DIAQUICK Multi-10/1 Drug Panel | Z06235CE | - 30 Panels (30x REF Z05235B) |
| | Z06236CE | - 10 Panels (10x REF Z05235B) |
| DIAQUICK Multi-10/2 Drug Panel | Z06102CE | - 30 Panels (30x REF Z06102B) |
| DIAQUICK Multi-10/3 Drug Panel | Z06103CE | - 30 Panels (30x REF Z06103B) |
| DIAQUICK Multi-10/4 Drug Panel | Z06104CE | - 30 Panels (30x REF Z06104B) |
| DIAQUICK Multi-10/5 Drug Panel | Z06105CE | - 30 Panels (30x REF Z06105B) |
| DIAQUICK Multi-10/6 Drug Panel | Z06106CE | - 30 Panels (30x REF Z06106B) |
| DIAQUICK Multi-10/7 Drug Panel | Z06107CE | - 30 Panels (30x REF Z06107B) |
| DIAQUICK DOA Multi-6 Cup | Z06667CE | - 1 Test |
| DIAQUICK Multi-5 Line Cassette | Z07001CE | - 30 Panels (30x REF Z07001B) |

Cardiac Markers

| | REF | Content |
|---------------------------------|----------|------------------------------|
| DIAQUICK Cardiac Combo Cassette | Z08234CE | - 20 Tests (20x REF Z08233B) |
| | Z08233CE | - 5 Tests (5x REF Z08233B) |
| DIAQUICK Troponin I Cassette | Z08120CE | - 30 Tests (30x REF Z08120B) |
| | Z08125CE | - 5 Tests (5x REF Z08120B) |

Tumour Markers

| | REF | Content |
|---------------------------------|----------|--|
| DIAQUICK AFP Cassette | Z06020CE | - 30 Tests (30x REF Z03020B) - 2x 3 mL Buffer |
| DIAQUICK CEA Cassette | Z06030 | - 30 Tests (30x Z03030B) - 2x 3 mL Buffer |
| DIAQUICK FOB Cassette | Z01101CE | - 25 Tests (25x Z01101B) - 25 Collection Tubes with Buffer |
| | Z01102CE | - 5 Tests (5x REF Z01101B) - 5 Collection Tubes with Buffer |
| DIAQUICK FOB-TRF Combi Cassette | J13101CE | - 20 Tests (20x J13101BN) - 20 Collection Tubes with Buffer |

Pregnancy / Fertility

| | REF | Content |
|------------------------------------|------------|--------------------------------|
| DIAQUICK hCG Cassette | Z98404CE | - 30 Tests (30x REF Z98404B) |
| DIAQUICK hCG Dipstick (5 mm) | J01402-1CE | - 50 Tests (50x REF J01402-1B) |
| DIAQUICK hCG Dipstick (3 mm) | J01402-2CE | - 50 Tests (50x REF J01402-2B) |
| DIAQUICK hCG Combo Cassette | Z01405CE | - 30 Tests (30x REF Z01405B) |
| DIAQUICK hCG Combo Dipstick (5 mm) | Z03403-1CE | - 50 Tests (50x REF Z03403-1B) |
| DIAQUICK hCG Combo Dipstick (3 mm) | Z03403-2CE | - 50 Tests (50x REF Z03403-2B) |
| DIAQUICK hCG Midstream | Z09800CE | - 30 Tests (30x REF Z09800B) |
| DIAQUICK LH Cassette | Z98502CE | - 30 Tests (30x REF Z98502B) |
| DIAQUICK LH Dipstick | Z06507CE | - 50 Tests (50x REF Z06507B) |

Others

| | REF | Content |
|--------------------------------|----------|---|
| DIAQUICK CRP Cassette | Z06021 | - 20 Tests (20x REF Z06021B) - 20 Extraction Tubes with Buffer |
| DIAQUICK Microalbumin Dipstick | Z08070CE | - 50 Tests (50x REF Z08070B) |

Infectious Diseases - ToRCH

| | | |
|-------------------------------|----------|--|
| DIAQUICK HSV 1/2 IgM Cassette | J15040CE | - 25 Tests (25x REF J15040B) - 1x 3 mL Buffer |
|-------------------------------|----------|--|

Rev.10

2017-09-28



EC DECLARATION OF CONFORMITY

We



Dialab Produktion und Vertrieb von chemisch – technischen Produkten und Laborinstrumenten Gesellschaft m. b. H.
IZ-NOE Sued, Hondastrasse, Objekt M55
2351 Wiener Neudorf, Austria

declare, on our own responsibility, that our products specified in the enclosed addendum "Other Products (Urine Strips), Rev.05 (1 page)", classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC:

Devices other than those covered by Annex II (Urine Strips)

meet the applicable provisions of the European Directive 98 / 79 / EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

CE marking has been carried out following the procedure referred to in Annex III of the aforesaid Directive.

This declaration is valid until 2019-04-12.

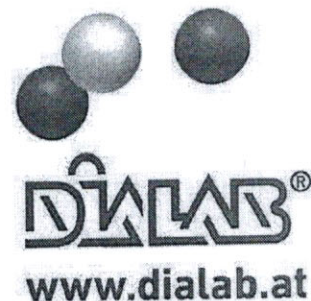
Wiener Neudorf, 2017-09-29



DIALAB
Produktion und Vertrieb von chemisch - technischen Produkten und Laborinstrumenten Gesellschaft m. b. H.
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Phone: +43 (0) 2236 660910, Fax: +43 (0) 2236 660910 - 30
E-Mail: office@dialab.at Website: www.dialab.at

DI Marlene Ramsey
Managing Director

**Addendum to the Declaration of Conformity for Other Products
(Urine Strips)**



URINE STRIPS

Strips

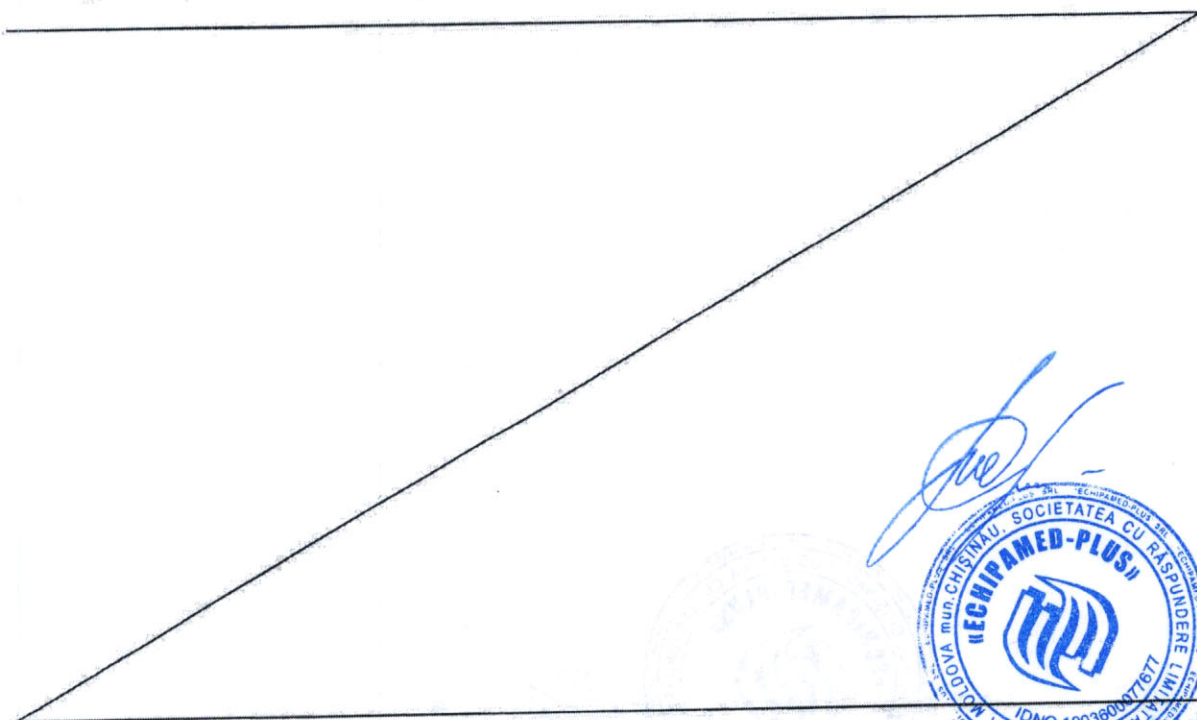
| | REF | CONT |
|-----------------|------------|-------------|
| Urine Strip 1 | G04001 | 100 strips |
| Urine Strip 2 | G04002 | 100 strips |
| Urine Strip 2A | G04002A | 50 strips |
| Urine Strip 2MC | G11002MC | 50 strips |
| Urine Strip 3A | G135003 | 50 strips |
| | G04003A | 100 strips |
| Urine Strip 4 | G04004 | 100 strips |
| Urine Strip 5 | G04005 | 50 strips |
| Urine Strip 4SG | G04004SG | 100 strips |
| Urine Strip 8 | G11008 | 50 strips |
| Urine Strip 9 | G04009 | 100 strips |
| Urine Strip 10C | G13510C | 50 strips |
| | G04010C | 100 strips |
| | G11010C | 150 strips |
| Urine Strip 11 | G04011 | 100 strips |
| | G11011 | 150 strips |

Strips with Mesh Technology

| | REF | CONT |
|------------------|--------------|-------------|
| Urine Strip 10ME | Z10010ME/BOX | 100 strips |

Urine Controls

| | REF | CONT |
|--|------------|-------------|
| Urine Comby Control <i>urine strip & analyser control (pos & neg)</i> | 798001 | 2x12 mL |



Other Products (Urine Strips), Rev.05

2017-09-29

Page 1 of 1