



To whom it may concern

Warsaw, January 22, 2014

Dear Ladies and Gentlemen,

We, Roche Diagnostics Polska Sp. z o. o., Warsaw seated at 6B Wybrzeże Gdynskie Str.; 01 - 531 Warsaw, Poland hereby certifies that

MIXED ENTERPRISE "BECOR" Limited Liability Company,

111/5 Calea Orheiului Street,
Mun. Chisinau, Republic of Moldova

is our official distributor in Moldova and is authorized to import and sell Roche Diagnostics products of the following product lines:

Applied Science
Professional Diagnostics
Molecular Diagnostics
Tissue Diagnostics

MIXED ENTERPRISE "BECOR" Limited Liability Company is also authorized to participate in tenders , promote, sell, provide warranty service, installation and repair all devices, accessories and reagents under the brand of Roche.

This Letter of Authorization is valid until revocation.

Yours faithfully

Roche Diagnostics Polska Sp. z o.o.



Roche Diagnostics Polska Sp. z o.o.

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Date: 2019.02.07 16:49:01 EET
Reason: MoldSign Signature
Location: Moldova




Renata Popielecka
Prokurent
Roche Diagnostics Polska sp. z o.o.

Roche Diagnostics Polska Sp. z o.o.
ul. Wybrzeże Gdynskie 6 B, 01-531 Warszawa
Tel. +48 22 481 55 55 (56)
Faks +48 22 481 55 99

Sąd Rejonowy dla m. st. Warszawy
w Warszawie, XII Wydział Gospodarczy
Krajowego Rejestru Sądowego,
KRS 0000132695

kapitał zakładowy 8 000 000 PLN
NIP 527-23-22-068
www.roche.pl

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Roche Professional Diagnostics
Sandhofer Straße 116
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)
Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/Product name: Combur¹⁰-Test UX

Art.-Nr./Id. No.: 11544373 (100 Tests)

Beschreibung/Description:

Zehnfach-Teststreifen zur semiquantitativen Bestimmung von spezifischer Dichte, pH, Leukozyten, Nitrit, Protein, Glucose, Keton, Urobilinogen, Bilirubin und Blut im Urin. Zur reflexionsphotometrischen Auswertung mit Urisys 1100 oder Urilux S Geräten und zur visuellen Ablesung. Nur für den Gebrauch durch Fachpersonal. Hinweis: Combur10 Test UX Teststreifen sind nicht für die Geräte Miditron, Miditron Junior und Miditron Junior II geeignet. Urisys 1100 oder Urilux S Geräte: Analysengeräte für die reflexionsphotometrische Auswertung von Urinesteststreifen.

Ten-patch test strip for the semi-quantitative determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketone bodies, urobilinogen, bilirubin and blood in urine. For evaluation by reflectance photometry with Urisys 1100 or Urilux S analyzer and for visual reading. For professional use only.

Note: Combur10 Test UX test strips are not suitable for use with Miditron, Miditron Junior and Miditron Junior II. Urisys 1100 or Urilux S analyzer: analyzer for reflectometric reading of urine test strips.

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.

to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 29 September 2011

Roche Diagnostics GmbH

ppa./on behalf of the company

i. V./on behalf of the company

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

Annerose Schenkel
Head of Quality Control Mannheim
Roche Diagnostics Global Operations

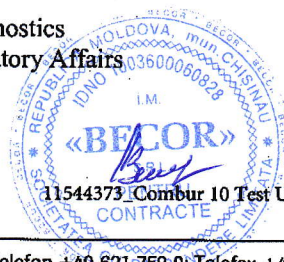
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Date: 2019.03.13 14:19:28 EET
Reason: MoldSign Signature
Location: Moldova



Kontaktadresse/Contact address: Roche Professional Diagnostics

Abt./Dept. Global Regulatory Affairs
Sandhofer Straße 116
D-68305 Mannheim
Fax: +49 621/759 1448

Roche Diagnostics GmbH Diagnostics Division



11544373_Combur 10 Test UX.doc/df

Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49 621 759 0; Telefax +49 621 759 2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher; Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan

**EG-Konformitätserklärung/EC Declaration of Conformity**

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Roche Professional Diagnostics
Sandhofer Straße 116
D-68305 Mannheim

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Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/Product name: Control-Test M

Art.-Nr./Id. No.: 11379194

Beschreibung/Description: Der Control-Test M-Kalibrationsstreifen dient zur Kalibration der Miditron M, Miditron Junior II, Supertron, Urilux S, cobas u 411, Urisys 1800 und Urisys 1100 Reflexionsphotometer und zur Überprüfung ihrer Leistung.
The Control-Test M calibration strip is used to perform the calibration of the Miditron M, Miditron Junior II, Supertron, Urilux S, cobas u 411, Urisys 1800 and Urisys 1100 reflectance photometers and to check the analyzers performance.

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.
to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 29.06.2007

Roche Diagnostics GmbH

ppa./on behalf of the company

Dr. M. Thein
Head of Quality & Regulatory
Management
Professional Diagnostics

i. V./on behalf of the company

A. Schenkel
Head of Quality Control
Professional Diagnostics

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Kontaktadresse/Contact address: Roche Professional Diagnostics
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Fax: +49 621/759 1448



control-test m. DOC-AJ

Roche Diagnostics GmbH

Roche Centralized Diagnostics
Sandhofer Strasse 116
D-68305 Mannheim
Telefon +49 - 621 - 759 0
Telefax +49 - 621 - 759 28 90

Registergericht Mannheim
HRB 3962
Aufsichtsrat:
Dr. Franz B. Humer, Vorsitzender

Geschäftsführung:
Dr. Jürgen Schwiezer, Vorsitzender
Dr. Manfred Baier,
Jürgen Redmann,
Peter-Claus Schiller,
Prof. Dr. Dr. Klaus Strein

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV SÜD Product Service GmbH (Ridlerstraße 65, 80339 München, Germany) als Notified Body (Nr. 0123)
as per Annex IV of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 via TÜV SÜD Product Service GmbH (Ridlerstrasse 65, 80339 Munich, Germany) as the Notified Body (No. 0123)

Hersteller/Manufacturer: Roche Diagnostics GmbH
Adresse/Address: Roche Professional Diagnostics
 Sandhofer Straße 116
 D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)
Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/Product name: Accutrend Cholesterol
Art.-Nr./Id. No.: 11418262 (25 tests)
 11418254 (5 tests)

Beschreibung/Description: Teststreifen zur quantitativen Cholesterin-Bestimmung aus frischem oder heparinisiertem frischen Kapillarblut. Ausschließlich für die Verwendung mit dem Accutrend GC, Accutrend GCT oder Accutrend Plus Messgerät. Zur Selbstabwendung geeignet.
Test strip for the quantitative determination of cholesterol in fresh or heparinised fresh capillary blood. Use only with the following meters: Accutrend GC, Accutrend GCT oder Accutrend Plus. Suitable for self-testing.

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.
to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 25.11.2010

Roche Diagnostics GmbH
 ppa./on behalf of the company

i. V. W. Prohmeder
 Dr. M. Thein
 Head of Quality
 Roche Professional Diagnostics

i. V./on behalf of the company

A. Schenkel
 Annerose Schenkel
 Head of Quality Control Mannheim
 Roche Diagnostics Global Operations

Kontaktadresse/Contact address: Roche Professional Diagnostics
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 Location: Moldova



EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV SÜD Product Service GmbH (Ridlerstraße 65, 80339 München, Germany) als Notified Body (Nr. 0123)
as per Annex IV of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998 via TÜV SÜD Product Service GmbH (Ridlerstrasse 65, 80339 Munich, Germany) as the Notified Body (No. 0123)

Hersteller/Manufacturer:

Roche Diagnostics GmbH

Adresse/Address:

Roche Professional Diagnostics
 Sandhofer Straße 116
 D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)
Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/Product name:

Accutrend® Glucose

Art.-Nr./Id. No.:

11447475 (25 tests)

Beschreibung/Description:

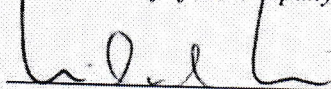
Teststreifen zur quantitativen In-vitro-Bestimmung des Blutzuckers aus frischem oder heparinisiertem Kapillarblut mit Accutrend Plus, Accutrend GCT, Accutrend GC oder Accutrend DM Messgeräten. Für medizinisches Fachpersonal oder Patienten. Zur Selbstanwendung geeignet.
Test strips for the in vitro quantitative determination of whole blood glucose in fresh or heparinised capillary blood with Accutrend Plus, Accutrend GCT, Accutrend GC, or Accutrend DM meters. For use by health care professionals or by patients. Suitable for self-testing.

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.
to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 07 May 2013

Roche Diagnostics GmbH

ppa./on behalf of the company



Dr. M. Thein
 Head of Quality
 Professional Diagnostics

i. V./on behalf of the company



A. Schenkel
 Head of Quality Control Mannheim
 Professional Diagnostics
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 Date: 2019.03.14 09:42:39 EET
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 Location: Moldova



KEKSvorlage Annex IV.doc - la

Roche Diagnostics GmbH

Diagnostics Division

Roche Diagnostics GmbH; Werk Penzberg; Nonnenwald 2; D 82377 Penzberg; Telefon +49 8856 60 0; Telefax +49 8856 60 3896

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher; Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 14 08 29670 029

Manufacturer:**Greiner Bio-One GmbH**

Bad Haller Straße 32
4550 Kremsmünster
AUSTRIA

Facility(ies):

Greiner Bio-One GmbH
Bad Haller Straße 32, 4550 Kremsmünster, AUSTRIA

**Product
Category(ies):**

**VACUETTE® Blood Collection System:
VACUETTE® Multiple Use Drawing Needles,
including VACUETTE® VISIO PLUS Needles**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.:

713041729_1

Valid from:

2014-08-12

Valid until:

2019-07-31



Hans-Heiner Junker



Date, 2014-08-13

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Date: 2019.02.15 14:33:06 EET
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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Greiner Bio-One GmbH
Maybachstr. 2
72636 Frickenhausen
Deutschland

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

**Design and development, manufacture, distribution and
installation of DNA chip systems for in vitro diagnostic
application and systems for sampling and storage
of specimens**

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2015-07-17

Certificate Registration No.: SX 60102255 0001

An audit was performed. Report No.: 21225071 001
Digitally signed by Lazari Cristina
Date: 2019.03.13 10:43:14 EET

This Certificate is valid until: 2018-04-28
BoldSign Signature
Location: Moldova


Certification Body

Date 2015-07-16




Dr. H. Lüdemann

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



Product Service

ZERTIFIKAT

Nr. Q4N 16 05 72713 003

Zertifikatsinhaber: Roche Diagnostics Deutschland GmbH
Vertrieb Diagnostics Deutschland

Sandhofer Str. 116
68305 Mannheim
DEUTSCHLAND

Betriebsstätte(n):

Roche Diagnostics Deutschland GmbH Vertrieb
Diagnostics Deutschland
Sandhofer Str. 116, 68305 Mannheim,
DEUTSCHLAND



**Zertifizierungs-
zeichen:**



Geltungsbereich:

Marketing, Vertrieb und Service von in-vitro
diagnostischen Systemen für Immunchemie,
Klinische Chemie, Klinische Histologie, Klinische
Cytologie, Point-of-Care und Eigenanwendung,
Molekulare Diagnostik und Gerinnung

**Angewandte
Norm(en):**

EN ISO 13485:2012 + AC:2012
Medizinprodukte - Qualitätsmanagementsysteme -
Anforderungen für regulatorische Zwecke
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

Die Zertifizierstelle von TÜV SÜD Product Service GmbH bescheinigt, dass das oben genannte Unternehmen ein Qualitätsmanagementsystem eingeführt hat und anwendet, das den Anforderungen der genannten Norm(en) entspricht. Umseitige Hinweise sind zu beachten.

Bericht Nr.: 713080774

Gültig ab: 2016-07-06
Gültig bis: 2019-07-05

Datum, 2016-06-14 **Stefan Preiß**



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Location: Moldova



Seite 1 von 1

DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Beneficiar: IMSP Centrul de Sănătate nr. 1 Orhei**Adresa:** mun. Orhei, str. Vasile Lupu 127**Data:** 18 aprilie 2019**GARANȚIE DE OFERTĂ nr. LG43565307100**

Banca Comercială "MOBIASBANCĂ – Groupe Société Générale" S.A., adresa juridică MD-2012, bd. Ștefan cel Mare și Sfânt, 81A, mun. Chișinău, Republica Moldova a fost informată că „BECOR” S.R.L. (numită în continuare „Ofertant”) urmează să înainteze oferta către Dvs. la data de 13 mai 2019 (numită în continuare „ofertă”) privind achiziția achiziția reactivelor și consumabilelor de laborator, conform Numărului de notificări: ocds-b3wdp1-MD-1555083058852.

La cererea Ofertantului, noi, Banca Comercială "MOBIASBANCĂ – Groupe Société Générale" S.A., prin prezenta, ne angajăm în mod irevocabil să vă plătim orice sumă sau sume ce nu depășesc în total suma de 1,000.00 (o mie, 00) MDL la primirea de către noi a primei solicitări din partea Dvs. în scris, însoțite de o declarație în care se specifică faptul că Ofertantul încalcă una sau mai multe dintre obligațiile sale referitor la condițiile ofertei, și anume:

- și-a retras oferta în timpul perioadei valabilității ofertei sau a modificat oferta după expirarea termenului-limită de depunere a ofertelor; sau
- fiind anunțat de către autoritatea contractantă, în perioada de valabilitate a ofertei, despre adjudecarea contractului: (i) eșuează sau refuză să semneze formularul contractului; sau (ii) eșuează sau refuză să prezinte garanția de bună execuție, dacă se cere conform condițiilor licitației, ori nu a executat vreo condiție specificată în documentele de atribuire, înainte de semnarea contractului de achiziție.

Această garanție va expira în cazul în care ofertantul devine ofertant câștigător, la primirea de către noi a copii înștiințării privind adjudecarea contractului și în urma emiterii Garanției de bună execuție eliberată către Dvs. la solicitarea Ofertantului.

Prezenta garanție este valabilă până la data de 12 iunie 2019 (inclusiv).

Cu respect,

Cornelia Rotari

Directorul Sucursalei Corporative
Banca Comercială „Mobiasbanca-Groupe Société Générale” S.A.

Executor:
Ceclu Ecaterina
Tel. 022-812-552



Digitally signed by Lazari Cristina
Date: 2019.04.24 15:50:31 EEST
Reason: MoldSign Signature
Location: Moldova



Bd. Ștefan cel Mare și Sfânt 81a
MD-2012, Chișinău, Moldova
Cod MOBBMD22
Cont de corespondență 35213892
la Centrul de Decontări al BNM

Contactell
+373 22 25 64 56
www.mobiasbanca.md

BC „Mobiasbanca – Groupe Société Générale” SA
Capital Social: 100 000 000 MDL
Număr de înregistrare de stat – 1002600006089



MD – 2020, or. Chişinău,
srt. Calea Orheiului 111/5
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МД 2020, г.Кишинэу,
ул. Калеа Орхеюлуй 111/5
тел. 406 - 299; 406 - 282
факс. 406 - 271
GSM 069140864
www.becor.md

Nr :14/19
Din :24.04.2019

Către: IMSP CS Nr 1 Orhei

In atenția : **Comisiei de evaluare a ofertelor de la LP Nr .ocds-b3wdp1-MD-1555083058852**

din 13.05.2019 pentru achizitionarea reactive si consumabile de laborator conform necesitatilor IMSP CS Nr 1 Orhei

Declarație

Prin prezenta, garantam:
ca termenul de valabilitate restant (la momentul livrării) va constitui 80% din termenul total de valabilitate al produsului nu mai puțin de 12 luni
Prezentarea mostrelor in termen de 3 zile de la solicitare

Multumim pentru colaborare!
Cu consideratie,

Iurie Bezer
Director ,IM Becor SRL
Ex.Lazari Cristina

Digitally signed by Lazari Cristina
Date: 2019.04.23 16:31:01 EEST
Reason: MoldSign Signature
Location: Moldova

