



This is to certify that the Quality Management System of:

**Avantor Fluid Handling B.V.**

Maidstone 50  
5026 SK Tilburg  
The Netherlands

applicable to:

**The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.**

has been assessed and approved by  
National Quality Assurance, U.S.A., against the provisions of:

**ISO 9001:2015**

For and on behalf of NQA, USA

Certificate Number: 16880  
EAC Code: 34  
Certified Since: March 22, 2012  
Valid Until: March 19, 2024  
Reissued: March 20, 2021  
Cycle Issued: March 20, 2021





# CERTIFICATE



This is to certify that



## VWR International Europe bv

Researchpark Haasrode 2020  
Geldenaaksebaan 464  
3001 Leuven  
Belgium

with the organizational units/sites as listed in the annex  
has implemented and maintains a **Quality Management System**.

### Scope:

Sales and supply of branded and private label chemicals, consumables, laboratory equipment, furniture, and medical devices from global leading developers and manufacturers of those products to customers in biopharma, healthcare, advanced technology and applied materials, education and government; manufacture of private label products, primarily laboratory and production chemicals including custom manufacturing solutions used in biopharmaceutical and industrial applications and production processes; provide value-added service offerings such as client outsourced activities: including sourcing and procurement, logistics, chemical and equipment tracking, lab and production services, scientific services and sample management; technical services in-house and at customer sites including installation, maintenance, qualification, calibration and repair of laboratory equipment

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

## ISO 9001 : 2015

Certificate registration no. 530840 QM15  
Valid from 2021-08-04  
Valid until 2024-06-28  
Date of certification 2021-08-04



### DQS GmbH

Markus Bleher  
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany



**Annex to certificate  
Registration No. 530840 QM15**

**VWR International Europe bv**

Researchpark Haasrode 2020  
Geldenaaksebaan 464  
3001 Leuven  
Belgium

<b>Location</b>	<b>Scope</b>
<b>530842 VWR International GmbH Graumanngasse 7 1150 Wien Austria</b>	Sales and supply; Lab and Production Services
<b>530843 VWR International GmbH Zimbagasse 5 1210 Wien Austria</b>	Distribution; Technical Services
<b>530841 VWR International bv Researchpark Haasrode 2020 Geldenaaksebaan 464 3001 Leuven Belgium</b>	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
<b>531223 VWR International GmbH Rue de Rive 18 1260 Nyon Switzerland</b>	Sales and supply
<b>531224 VWR International GmbH Grabenstraße 1 8952 Schlieren Switzerland</b>	Sales and supply; Distribution; Lab and Production Services; Technical services
<b>531221 VWR International GmbH Lerzenstraße 16 / 18 8953 Dietikon Switzerland</b>	Sales and supply

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.



## Annex to certificate Registration No. 530840 QM15

### VWR International Europe bv

Researchpark Haasrode 2020  
Geldenaaksebaan 464  
3001 Leuven  
Belgium

Location	Scope
<b>530844</b> VWR International s.r.o. Praská 442 281 67 Stribrná Skalice Czech Republic	Sales and supply; Distribution; Kitting Services; Technical services
<b>530847</b> VWR International s.r.o. Pivovarská 30 75661 Rožnov prod Radhoštěm Czech Republic	Sales and supply
<b>530868</b> VWR International GmbH Großenhainer Straße 99 01127 Dresden Germany	Sales and supply
<b>530869</b> VWR International GmbH Wöhlerstraße 42 30163 Hannover Germany	Sales and supply
<b>530867</b> VWR International GmbH Hilpertstraße 20A 64295 Darmstadt Germany	Sales and supply; Lab and Production Services; Technical services
<b>539946</b> VWR International GmbH Heinrich-Blanc-Straße 40 76646 Bruchsal Germany	Distribution

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<b>Location</b>	<b>Scope</b>
<b>530865</b> <b>VWR International GmbH</b> <b>John-Deere-Straße 5</b> <b>76646 Bruchsal</b> <b>Germany</b>	Sales and supply; Distribution
<b>530866</b> <b>VWR International GmbH</b> <b>Vichystraße 2</b> <b>76646 Bruchsal</b> <b>Germany</b>	Distribution
<b>530870</b> <b>VWR International GmbH</b> <b>Fraunhoferstr.11</b> <b>85737 Ismaning</b> <b>Germany</b>	Sales and supply
<b>530871</b> <b>VWR International GmbH</b> <b>James-Franck-Ring 9</b> <b>89081 Ulm</b> <b>Germany</b>	Sales and supply
<b>530859</b> <b>VWR International A/S</b> <b>Tobaksvej 21</b> <b>2860 Søborg</b> <b>Denmark</b>	Sales and supply; Distribution; Lab and Production Services; Technical services
<b>531213</b> <b>VWR International Eurolab, S.L.</b> <b>C/ De la Tecnología, 5-17A7 - Llinars Park</b> <b>08450 Llinars Del Vallès Barcelona</b> <b>Spain</b>	Sales and supply; Distribution; Lab and Production Services; Technical services

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<b>Location</b>	<b>Scope</b>
<b>530860 VWR International Oy Valimotie 9 00380 Helsinki Finland</b>	Sales and supply; Distribution; Lab and Production Services; Technical services
<b>530863 VWR International S.A.S. Europarc 26 Avenue Leonard de Vinci 33608 Pessac Cedex France</b>	Sales and supply
<b>530861 VWR International S.A.S Chemin de la Croix Saint-Marc Z.I. de Vaugereau 45250 Briare-le-Canal France</b>	Distribution; Manufacture
<b>530862 VWR International S.A.S Immeuble Estréo, 1-3 Rue d'Aurion 93110 Rosny-sous-Bois France</b>	Sales and supply; Lab and Production Services; Technical services
<b>531226 VWR International Ltd VWR House Warren Court Feldspar Close Enderby LE19 4SD Leicester United Kingdom</b>	Sales and supply

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<b>Location</b>	<b>Scope</b>
<b>531228 LAB3 Service 1 Dragon Court Crofts End Road St George Bristol BS5 7XX United Kingdom</b>	Lab and Production Services; Technical services
<b>531225 VWR International Ltd. Customer Service Centre Hunter Boulevard Magna Park Lutterworth, Leicestershire LE17 4 XN United Kingdom</b>	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
<b>531227 VWR International Ltd. 14 Media Village Liscombe Park Soulbury Leighton Buzzard LU7 0GA United Kingdom</b>	Sales and supply
<b>540366 VWR International Medical Equipment Supplies and Management The Solutions Buckshaw Village, Chorley Chorley PR7 7EL United Kingdom</b>	Sales and supply; Distribution; Technical Services

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**Location**

**Scope**

**531229**

**Basan - the cleanroom division of VWR  
Units 2 & 3 Newton Court  
Basingstoke  
RG24 8GF  
United Kingdom**

Sales and supply;  
Distribution;  
Manufacture

**546015**

**Hichrom Ltd  
1-3 The Markham Centre, Station Road,  
Theale,  
Reading, Berkshire  
RG7 4AB  
United Kingdom**

Manufacture of UHPLC and HPLC columns  
with lot traceability. Procurement and  
distributor for UHPLC and HPLC columns  
and associated solvents, packing materials  
and accessories with lot traceability

**531198**

**VWR International Kft.  
Simon László utca 4  
4034 Debrecen  
Hungary**

Sales and supply;  
Distribution;  
Lab and Production Services;  
Technical services

**531199**

**VWR International Ltd  
Orion Business Campus  
Northwest Business Park  
Ballycoolin, Blanchardstown  
Dublin 15  
Ireland**

Sales and supply;  
Distribution;  
Lab and Production Services;  
Technical services

**531200**

**VWR International (Northern Ireland) Ltd  
19 Clarendon Street  
Derry BT4 87EP  
Ireland**

Sales and supply



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**VWR International Europe bv**

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Belgium

<b>Location</b>	<b>Scope</b>
<b>531201 VWR International s.r.l. Via San Giusto 85 20153 Milano Italy</b>	Sales and supply; Lab and Production Services; Technical Services; Manufacture
<b>531203 VWR International B.V. Orlyplein 85 1043 AP Amsterdam Netherlands</b>	Sales and supply; Lab and Production Services; Technical services
<b>531205 VWR International AS Brynsalleen 4 0667 Oslo Norway</b>	Sales and supply; Lab and Production Services; Technical services
<b>531206 VWR International AS Kokstadflaten 35 5152 Bønes (Bergen) Norway</b>	Sales and supply
<b>531207 VWR International AS Leirfossvegen 27 7038 Trondheim Norway</b>	Sales and supply
<b>531211 VWR International Sp. z. o.o. Limbowa 5 80-175 Gdańsk Poland</b>	Sales and supply; Lab and Production Services; Technical services

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<b>Location</b>	<b>Scope</b>
<b>531212 VWR International Sp. z. o.o. Aleja Niepodległości 606/610 81-879 Sopot Poland</b>	Distribution
<b>531208 VWR International Material De Laboratorio, LDA Centro Empresarial de Alfragide Rua da Industria, n° 6 2610-088 Alfragide Portugal</b>	Sales and supply; Distribution; Lab and Production Services; Technical services
<b>531217 VWR International AB Fagerstagatan 18A 163 94 Stockholm Sweden</b>	Sales and supply; Lab and Production Services; Technical services
<b>531220 VWR International AB Skiffervägen 12 224 78 Lund Sweden</b>	Sales and supply
<b>531218 VWR International AB Varbergsgatan 2 412 65 Göteborg Sweden</b>	Sales and supply
<b>531219 VWR International AB Nordiskt Centrallager Gjuterigatan 3 (Bofors Industriområde) 691 50 Karlskoga Sweden</b>	Distribution

This annex (edition: 2021-08-04) is only valid in connection with the above-mentioned certificate.

Avantor Performance Materials Poland Spółka Akcyjna  
Sowińskiego 11  
44-101 Gliwice  
Tel. 48 32 2392 000

## Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street  
44-101, Gliwice  
Poland

Herewith declares the following:

Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard. This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices. The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking

Gliwice, Poland

January 25, 2019

A handwritten signature in blue ink that reads 'Anna Szuba'.

Anna Szuba  
Quality Director



**J.T.Baker product list for CE marked products**

<b>Product</b>	<b>Product number</b>	<b>Pack size</b>
<b>Diluents</b>		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
	3969-00	20 L
Diluid™ Abacus	3430.9020	20 L
	3430.9010	10 L
	3430-00	20 L
Diluid™ AC 900	3996	20 L
Diluid™ APR	3476.9020PC	20 L
Diluid™ Azide free	3957	20 L
Diluid™ III Diff	3963	20 L
	3963.9010	10 L
	3963-00	20 L
Diluid™ Erma	3459.9020	20 L
	3459-00	20 L
Diluid™ Mindray	3439.9020PC	20 L
	3439-00	20 L
Diluid™ NR	3483.9020PC	20 L
	3483-00	20 L
Diluid™ Ruby	2987.9020PC	20 L
Diluid™/Sheath 3200-4000	3832.9020	20 L
Diluid™ ST1600/2000	3976	20 L
Sheath D	3495.9010PC	10 L
Sheath Fluid 3000/3500	3471.9020PC	20 L
<b>Lyses</b>		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22 CN Free	2986.0500PE	500 ml
CyMet™ 3000	3469.9010PC	10 L
CyMet™ 3200 CN free	3823.1000	1 L
CyMet™ 3500	3839.5000PC	5 L
CyMet™ 3500 CN free	3825	5 L
CyMet™ 610 CN free	3970	10 L
	3970-00	10 L
	3977	5 L
CyMet™ Abacus CN free	3431.1000	1 L
	3431-00	1 L
CyMet™ APR Baso II	3479.1000PE	1 L
CyMet™ APR CN free	3417.0500PE	500 ml
CyMet™ APR EO	3478.1000PE	1 L
CyMet™ ASA	2950.2500PE	2.5 L
CyMet™ ASB	2951.0500PE	500 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3968	1 L
	3968-00	500 ml
CyMet™ III Diff CN free	3511.1000	1 L
	3511-00	5 L
CyMet™ Erma	3416-00	500 ml
	3416.0500	500 ml
CyMet™ H20	3853.1000	1 L
CyMet™ KX CN Free	3425-00	500 ml
	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
	3863-00	1 L micros
CyMet™ Mindray	3441-00	500 ml
CyMet™ Mindray CN Free	3440.0500PE	500 ml



**J.T.Baker product list for CE marked products**

<b>Product</b>	<b>Product number</b>	<b>Pack size</b>
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	3486-00	1 L
	3486.1000PE	1 L
CyMet™ NR V	3485.1000PE	1 L
CyMet™ Ruby CN Free	2988.5000PC	5 L
CyMet™ ST 1600/2000 CN free	3759.5000	5 L
LeucoLyse	3475.5000PC	5 L
LeucoLyse Ruby	2989.5000PC	5 L
<b>Cleaners</b>		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3900-00	5 L
	3768,1000	1 L micros
ProClean™ Abacus	3432,5000	5 L
	3432.1000PE	1 L
ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862,5000	5 L
	3862.9020PC	20 L
	3862-00	5 L
	3867-00	1 L micros
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
<b>Hematology Controls</b>		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control 4xN	3747	4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751	6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635	2.5 ml
3-Diff Control L/N/H	3433/3434/3435	2.5 ml
	3502/3503/3504	4.5 ml
3-Diff Control extended L/N/H	3421/3422/3423	2.5 ml
CD-Diff Control L/N/H	3452/3453/3454	3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838	6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457	2.5 ml
Platelet Control- Extended value	3424	5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699	3.0 ml
XE-Diff Control L/N/H	3731/3732/3733	4.5 ml
<b>Fixatives</b>		
Cervix Spray Fixative	3869,1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933,1000	1 L
	3933.5000PC	5 L
	3933,9010	10 L
	3933,9020	20 L
	3933.1000MB	1000 L
	3933.9020PE	20 L
	3933.9010JL	10 L
	3933.9020JL	20 L
<b>Clearing agents</b>		
UltraClear™	3905.2500PE	2.5 L
	3905.5000PE	5 L
	3905.9010PE	10 L

**J.T.Baker product list for CE marked products**

<b>Product</b>	<b>Product number</b>	<b>Pack size</b>
<b>Stains and Dyes</b>		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
<b>Mounting media</b>		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
<b>PBS</b>		
PBS	3059	20 L
	3059.9010PC	10 L



## Declaration of CE conformity

Avantor Performance Materials B.V. reg. no. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20  
7418 AM Deventer  
The Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T.Baker<sup>®</sup> label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III. The BeneSphera<sup>™</sup> 3 Part Diff Analyzer H32 is in compliance with IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use.

The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self-registration.

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

January 6, 2015

Dr. J. Mittendorf  
QA & RA Manager

## J.T.Baker® product list for CE marked products

Product no.	Product	Pack size
<b>Hematology Analyzer</b>		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
<b>Clinical Chemistry Analyzer</b>		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
<b>Diluents</b>		
3961	Diluid 100 Plus	20 liter
2990.9010PC	Diluid™ 22	10 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9020	Diluid Abacus	20 liter
3430.9010	Diluid Abacus	10 liter
3996	Diluid AC 900	20 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
2901.9010PC	Diluid BS34	10 liter
3963	Diluid III Diff	20 liter
3963.9010	Diluid III Diff	10 liter
3459.9020	Diluid Erma	20 liter
3419.9020PC	Diluid M5	20 liter
3439.9020PC	Diluid Mindray	20 liter
3483.9020PC	Diluid NR	20 liter
2987.9020PC	Diluid Ruby	20 liter
3832.9020	Diluid/Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3495.9010PC	Sheath D	10 liter
3471.9020PC	Sheath Fluid 3000/3500	20 liter
<b>Lyses</b>		
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet 1000 CN free	5 liter
2986.0500PE	CyMet™ 22	500 ml
3469.9010PC	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3839.5000PC	CyMet 3500	5 liter
3825	CyMet 3500 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3417.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
2950.2500PE	CyMet ASA	2.5 liter
2951.0500PE	CyMet ASB	500 ml
2952.9010PC	CyMet AS CN Free	10 liter
3755	CyMet Automated	5 liter
2982.0500PE	CyMet BS3 CN free	500 ml
2902.1000PE	CyMet BS34 CN Free	1 liter
3968.0500	CyMet III Diff	500 ml
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3511.1000	CyMet III Diff CN free	1 liter
3511.5000	CyMet III Diff CN free	5 liter

3416.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3853.1000	CyMet H20	1 liter
3425.0500	CyMet KX CN Free	500 ml
2985.1000PE	CyMet LH 53	1 liter
3489.1000PE	CyMet MBA	1 liter
3418.1000PE	CyMet MD(I)	1 liter
2984.1000PE	CyMet MD(I) 53	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3497.0500PE	CyMet MH CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3863.1000	CyMet Micro CN free	1L micros
3441.0500PE	CyMet Mindray	500 ml
3440.0500PE	CyMet Mindray CN Free	500 ml
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
2988.5000PC	CyMet Ruby CN Free	5 liter
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3788	CyMet STX/STL	1 liter
3475.5000PC	LeucoLyse	5 liter
2989.5000PC	LeucoLyse Ruby	5 liter
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3513.1000PE	RBCLyse™	1 liter
3518G.1000PE	RBCLyse G	1 liter
3514.0500PE	WBCStabilise™	500 ml
<b>Reticulocyte Reagents</b>		
3493.1000PE	RetiClear™ MHG	1 liter
3774	RetiCount™	30 ml
2953.0210PE	RetiCount AS	210 ml
3777	RetiCount CD	15 x 3.5 ml
3494.0200PE	RetiCount G	200 ml
<b>Cleaners</b>		
3507.9020	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3763	DetectoTerge™	5 liter
3766	DetectoTerge	1 liter
2970.0900PE	DetectoTerge BS	900 ml
3917	HypoChlorite	5 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3432.1000PE	ProClean Abacus	1 liter
3432.5000	ProClean Abacus	5 liter
3902.0100PE	ProClean CD	100 ml
3862.9020PC	ProClean Extra	20 liter
3862.5000	ProClean Extra	5 liter
3862.1000	ProClean Extra	1 liter
3867.1000PE	ProClean Extra	1L micros
3498.1000PE	ProClean MX5	1 liter
3901	ProClean Plus	100 ml
3442.5000PE	Rinse Mindray	5 liter

Product no.	Product	Pack size
<b>Reagent Packs</b>		
2910	Reagent Pack BS34	1 pack
<b>Hematology Controls and Calibrators</b>		
3427/3428/3429	8-Parameter Control L/N/H	2.5 ml
3463/3464/3465	8-Parameter Control L/N/H	2.5 ml
3701/3702/3703	8-Parameter Control L/N/H	4.5 ml
3746	8-Parameter Control L+N+H	3 x 2.5 ml
3747	8-Parameter Control 4xN	4 x 2.5 ml
3751	8-Parameter Control 1xL+4xN+1xH	6 x 2.5 ml
3633/3634/3635	8-Parameter Control ext L/N/H	2.5 ml
3433/3434/3435	3-Diff Control L/N/H	2.5 ml
3502/3503/3504	3-Diff Control L/N/H	4.5 ml
3466	3-Diff Control 4xL	4 x 2.5 ml
3467	3-Diff Control 4xN	4 x 2.5 ml
3468	3-Diff Control 4xH	4 x 2.5 ml
3421/3422/3423	3-Diff Control ext L/N/H	2.5 ml
3681/3682/3683	5D Control L/N/H	5.0 ml
3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3613/3614/3615	BC-Diff 5 Control L/N/H	4.5 ml
3940	Cal Set 1	2 x 2.5 ml
3452/3453/3454	CD-Diff Control L/N/H	3.0 ml
3838	CD-Diff Control 2xL+2xN+2xH	6 x 3.0 ml
3455/3456/3457	K-Diff Control L/N/H	2.5 ml
3424	Platelet Control Ext. value	5 x 3 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3652/3653/3654	XE-RET Control L/N/H	3.0 ml

Product no.	Product	Pack size
<b>Stains and Dyes</b>		
3800.1000PE	Eosin-Y Alcoholic	1 liter
3800.2500PE	Eosin-Y Alcoholic	2.5 liter
3800.9200	Eosin-Y Alcoholic	200 liter
3446.1000PE	Eosin Y 0.5% Aqueous	1 liter
3446.9200	Eosin Y 0.5% Aqueous	200 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3856.9180ST	Giemsa	180 liter
3870.1000	Hematoxyline (Mayer)	1 liter
3870.2500	Hematoxyline (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3873.9200	Hematoxyline (Harris, Gill II)	200 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	500 ml
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
<b>Clearing agent</b>		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
<b>Mounting media</b>		
3921.0500	UltraKitt™	500 ml
3921.0600	UltraKitt	6 x 100 ml
3921.9025ST	UltraKit	25 liter
3882.0500	Mounting Medium High	500 ml
3883.0500	Mounting Medium Low	500 ml
<b>Fixatives</b>		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010PE	10% v/v Buffered Formaldehyde	10 liter
3933.9020	10% v/v Buffered Formaldehyde	20 liter
3933.9200	10% v/v Buffered Formaldehyde	200 liter
3880.1000	Bouin's Fixative	1 liter
3869.1200	Cervix Fixative	12 x 125 ml
3884.9010PC	Cytology Fixative LBCM	10 liter
3409.9010	Immuno PBS 20x concentrated	10 liter
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter



# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Laboratories Diagnostics Division  
100 Abbott Park Road  
Abbott Park  
Illinois  
60064  
USA

Holds Certificate Number:

FM 743464

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.**

For and on behalf of BSI:

\_\_\_\_\_  
Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2018-10-12

Latest Revision Date: 2022-04-12

Effective Date: 2021-10-13

Expiry Date: 2024-10-12

Page: 1 of 2



...making excellence a habit.™

Certificate No: FM 743464

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC Inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.

Original Registration Date: 2018-10-12

Latest Revision Date: 2022-04-12

Effective Date: 2021-10-13

Expiry Date: 2024-10-12

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abbott Laboratories Diagnostics Division  
100 Abbott Park Road  
Abbott Park  
Illinois  
60064  
USA

Holds Certificate Number:

**MD 743461**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-06-01

Latest Revision Date: 2022-06-22

Effective Date: 2021-10-13

Expiry Date: 2024-10-12

Page: 1 of 2



...making excellence a habit.™

Certificate No: **MD 743461**

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan	Design and Development of in vitro diagnostics products including test kits and reagents.

Original Registration Date: 2021-06-01

Latest Revision Date: 2022-06-22

Effective Date: 2021-10-13

Expiry Date: 2024-10-12

Page: 2 of 2

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.



## Declaration of Conformity

**Certificate Identification:** SC-09H46  
**Legal Manufacturer's Name:** Abbott Laboratories  
Diagnostics Division  
**Legal Manufacturer's Address:** Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H46-02	58236	CELL-DYN Emerald CLEANER	Self-declared
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	Self-declared
09H48-02	58237	CELL-DYN Emerald DILUENT	Self-declared

<b>Authorized European Representative (Name and Address)</b>	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
<b>Harmonized Standards</b>	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature:

Signature:

Full Name:

Barry Simpson

Full Name:

Marcy Jaqua

Position:

Site Quality Manager

Position:

Director, Regulatory Affairs

Date of Approval:

02. Dec. 2015

Date of Approval:

01 DEC 2015

Date Issued:

**DEC 02 2015**

Place Issued:

Abbott Santa Clara

Supersedes:

IRIS V6  
July 6, 2015

Effective (Date or Lot Number):

**DEC 03 2015**



# EC Certificate

**Full Quality Assurance System  
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,  
Annex IV excluding (4, 6)**

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG  
Valenciener Str. 11  
52355 Düren  
Germany

Products: Products for self-testing  
- Single and multi-parameter disposable test strips for urine analysis  
- Indicator test strips and papers for measurement of pH in urine

Replaces Certificate, Registration No.: HL 60119814 0001

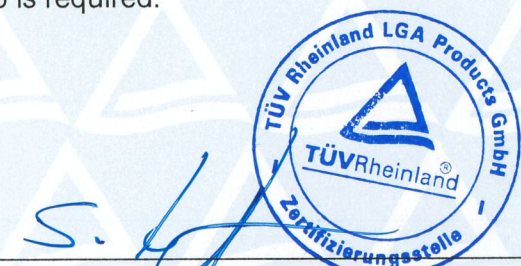
The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



Dipl.-Ing. Sven Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.



# EC Certificate

**Full Quality Assurance System  
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,  
Annex IV excluding (4, 6)**

Registration No.: HL 1038121-1

Manufacturer: MACHEREY-NAGEL GmbH & Co. KG  
Valenciener Str. 11  
52355 Düren  
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MACHEREY-NAGEL GmbH & Co. KG Valenciener Str. 11 52355 Düren Germany	Design and development, manufacture and quality control
/02	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



TÜV Rheinland LGA Products GmbH  
TÜVRheinland®  
Zertifizierungsstelle

Dipl.-Ing. Sven Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.



# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

including the locations according to annex

Scope: Design and development, production and distribution  
of products for filtration, rapid tests, water analysis,  
chromatography and bioanalysis

Proof has been furnished by means of an audit that the  
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-05-29 until 2023-05-28.

2020-05-25



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valenciennener Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis. Service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2020-05-25

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln





ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ  
(РОСЗДРАВНАДЗОР)

## РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 07 декабря 2015 года № ФСР 2011/11306

На медицинское изделие

**Краситель Азур-Эозин по Романовскому (МиниМед-Р)  
по ТУ 9398-003-29508133-2011**

Настоящее регистрационное удостоверение выдано

**Общество с ограниченной ответственностью "МиниМед"  
(ООО "МиниМед"), Россия,**

**241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А**

Производитель

**Общество с ограниченной ответственностью "МиниМед"  
(ООО "МиниМед"), Россия,**

**241520, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д. 17А**

Место производства медицинского изделия

**241520, Брянская область. Брянский район, с. Супонево, пер. Комсомольский,  
д. 7, корп. 2-а**

Номер регистрационного досье № РД-9275/51846 от 18.11.2015

Вид медицинского изделия 232730

Класс потенциального риска применения медицинского изделия 3

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 07 декабря 2015 года № 9111  
допущено к обращению на территории Российской Федерации.

**Руководитель Федеральной службы  
по надзору в сфере здравоохранения**

**М.А. Мурашко**

**0015715**





ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ  
И СОЦИАЛЬНОГО РАЗВИТИЯ

## РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ

№ ФСР 2011/11336

от 15 июля 2011 года

Срок действия: не ограничен.

Настоящее удостоверение выдано

ООО "МиниМед",

Россия, 241520, Брянская область, Брянский район,  
г. Брянск, село Супонево, ул. Шосейная, д.17, корп. А

и подтверждает, что изделие медицинского назначения

Краситель - фиксатор эозин метиленовый синий по Май-Грюнвальду  
(МиниМед-М-Г) по ТУ 9398-004-29508133-2011

производства

ООО "МиниМед",

Россия, 241520, Брянская область, Брянский район,  
г. Брянск, село Супонево, ул. Шосейная, д.17, корп. А

класс потенциального риска 3

ОКП 93 9816

соответствующее комплекту регистрационной документации

КРД № 18884 от 24.05.2011

приказом Росздравнадзора от 15 июля 2011 года № 4261-Пр/11

разрешено к производству, продаже и применению на территории Российской Федерации

Врио руководителя Федеральной службы  
по надзору в сфере здравоохранения  
и социального развития







241520, г. Брянск, Супонево, пер. Комсомольский, 4  
 Т/ф (4832) 41-63-56, 41-67-02, 92-96-94, 92-97-03,  
 E.m.: info@minimed.debryansk.ru www.minimed.ru

Р/с 40702810308000100320 Брянское ОСБ № 8605 г. Брянск  
 К/с 30101810400000000601 ИНН 3234007127 БИК 041501601  
 КПП 320701001 ОКПО 29508133

ПАСПОРТ №

**Фиксатор – краситель эозин метиленовый синий по  
 Май-Грюнвальду**

Серия № \_\_\_\_\_

Дата изгот. \_\_\_\_\_

Срок годности 1 год

Испытания проведены по ТУ 9398-004-29508133-6

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид	Сиропобразная жидкость темно-синего цвета	соответствует
2. Время фиксации мазка, мин.	2-3 мин.	соответствует
3. Время наступления окраски мазка, не более	15 мин.	соответствует
4. Плотность при 20° С, г/л	0,795-0,85	
5. Окраска форменных элементов крови	Исп. по п.3,5,2,2 настоящих ТУ	

Заключение: качество продукта соответствует ТУ

Начальник ОТК



**КОПИЯ  
 ВЕРНА**





Certificate JP06/040143

The management system of

**ERMA INC.**

3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**  
**EN ISO 13485:2016**



For the following activities

- 1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers**
- 2. Distribution of in-vitro diagnostic products for hemoglobin measurement**

This certificate is valid from 16 November 2021 until 16 November 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 10. Certified since 16 November 2006

Authorised by



0005

SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

21HC 13485 2016 0421

Page 1 of 1



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*Certificate of Completion*

*This is to certify*

*Mr. Alexei Legun*

*Has successfully completed*

*The technical maintenance training course*

*On*

*Fully Automatic Blood Cell Counter*

*PCE-210*

*Particle(Blood Cell)Counter*

*PCE-170/PCE-170N*

*Hemoglobin meter*

*H6-20N*

*March 24, 2005*

*H. Shimosaka*

*Hiroshi Shimosaka*

*President*

*ERMA INC.*

