

## 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



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



**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

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

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

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

<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

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

<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

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**

**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



**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>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

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

<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.



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

