

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[®] 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[™] 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
Hematology Analyzer		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
Clinical Chemistry Analyzer		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
Diluents		
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
Lyses		
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
Reticulocyte Reagents		
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
Cleaners		
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
Reagent Packs		
2910	Reagent Pack BS34	1 pack
Hematology Controls and Calibrators		
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
Stains and Dyes		
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
Clearing agent		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
Mounting media		
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
Fixatives		
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

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

Location	Scope
530842 VWR International GmbH Graumanngasse 7 1150 Wien Austria	Sales and supply; Lab and Production Services
530843 VWR International GmbH Zimbagasse 5 1210 Wien Austria	Distribution; Technical Services
530841 VWR International bv Researchpark Haasrode 2020 Geldenaaksebaan 464 3001 Leuven Belgium	Sales and supply; Distribution; Manufacture; Lab and Production Services; Technical services
531223 VWR International GmbH Rue de Rive 18 1260 Nyon Switzerland	Sales and supply
531224 VWR International GmbH Grabenstraße 1 8952 Schlieren Switzerland	Sales and supply; Distribution; Lab and Production Services; Technical services
531221 VWR International GmbH Lerzenstraße 16 / 18 8953 Dietikon Switzerland	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
530844 VWR International s.r.o. Praská 442 281 67 Stribrná Skalice Czech Republic	Sales and supply; Distribution; Kitting Services; Technical services
530847 VWR International s.r.o. Pivovarská 30 75661 Rožnov prod Radhoštěm Czech Republic	Sales and supply
530868 VWR International GmbH Großenhainer Straße 99 01127 Dresden Germany	Sales and supply
530869 VWR International GmbH Wöhlerstraße 42 30163 Hannover Germany	Sales and supply
530867 VWR International GmbH Hilpertstraße 20A 64295 Darmstadt Germany	Sales and supply; Lab and Production Services; Technical services
539946 VWR International GmbH Heinrich-Blanc-Straße 40 76646 Bruchsal Germany	Distribution

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Registration No. 530840 QM15**

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

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

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

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

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

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



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VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

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

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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

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

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

VWR International Europe bv

Researchpark Haasrode 2020
Geldenaaksebaan 464
3001 Leuven
Belgium

Location

Scope

**531212
VWR International Sp. z. o.o.
Aleja Niepodległości 606/610
81-879 Sopot
Poland**

Distribution

**531208
VWR International
Material De Laboratorio, LDA
Centro Empresarial de Alfragide
Rua da Industria, n° 6
2610-088 Alfragide
Portugal**

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

**531217
VWR International AB
Fagerstagatan 18A
163 94 Stockholm
Sweden**

Sales and supply;
Lab and Production Services;
Technical services

**531220
VWR International AB
Skiffervägen 12
224 78 Lund
Sweden**

Sales and supply

**531218
VWR International AB
Varbergsgatan 2
412 65 Göteborg
Sweden**

Sales and supply

**531219
VWR International AB
Nordiskt Centrallager
Gjuterigatan 3 (Bofors Industriområde)
691 50 Karlskoga
Sweden**

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



CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:

9362-8

Initial Certification Date:

March 28, 2012

Date of Certification Decision:

March 24, 2021

Issuing Date:

March 27, 2021

Valid Until:

March 27, 2024



Intertek



Calin Moldovean

President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2066395-1

Organization: Kai Industries Co., Ltd.
1110 Oyana
Seki City, Gifu
501-3992 Japan

Scope: Design and Development, Manufacture and Distribution of Surgical Blades, Scalpels, Biopsy Punches, Dermal Curettes, Micro Surgical Scalpels, Perforators for Dental Use, Microtome Blades and Prep Razors

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150245830-301
Effective date: 2021-12-01
Expiry date: 2024-11-30
Issue date: 2021-11-26



Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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
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21HC 13485 2016 0421

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