

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 basis 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
Digitally signed by Ceaicovschi Tudor
Date: 2025.02.18 14:22:08 EET
Reason: MoldSign Signature
Location: Moldova
June 14, 2016
MOLDOVA EUROPEANĂ



Anna Szuba

Quality Director

Deklaracja zgodności WE

Avantor Performance Materials Poland S.A. producent odczynników do diagnostyki in vitro zlokalizowany:

ul. Sowińskiego 11

44-101, Gliwice

Polska

Deklaruje zgodność odczynników wymienionych w załączonej liście oznakowanych etykietą J.T.Baker z wymaganiami Dyrektywy 98/79/WE Parlamentu Europejskiego i Rady w sprawie wyrobów medycznych używanych do diagnostyki in vitro oraz wymaganiami normy ISO 13485.

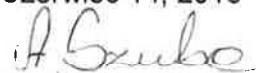
Powyższe odczynniki są oznakowane etykietą J.T.Baker i posiadają znaki CE na etykiecie.

Produkty nie są częścią wykazu A i wykazu B załącznika II Dyrektywy dla wyrobów medycznych do diagnostyki in vitro z Dyrektywy 98/79/WE Parlamentu Europejskiego i Rady, ale podlegają rejestracji.

Deklaracja obowiązuje dla wszystkich wyrobów medycznych do diagnostyki in vitro opisanych powyżej oraz wprowadzonych na rynek i posiadających oznakowanie CE.

Gliwice, Polska.

Czerwiec 14, 2016



Anna Szuba

Dyrektor Jakości

J.T.Baker product list for CE marked products

Product	Product Number	Pack Size
Hematology Analyzers		
H32 3-Part Differential	2983	1 unit
Diluents		
Diluid™ 100 Plus	3961	20 L
Diluid™ 22	2990.9010PC	10 L
Diluid™ 610	3969	20 L
Diluid™ Abacus	3430.9020	20 L
	3430.9010	10 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
Diluid™ Erma	3459.9020	20 L
Diluid™ Mindray	3439.9020PC	20 L
Diluid™ NR	3483.9020PC	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
Lyses		
CN-free Lyse Diff AC 900	3998	5 L
CyMet™ 22	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
	3977	5 L
CyMet™ Abacus CN free	3431.1000	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	3.8 L
CyMet™ ASB	2951.0250PE	380 ml
CyMet™ AS CN free	2952.9010PC	10 L
CyMet™ BS3 CN free	2982.0500PE	500 ml
CyMet™ III Diff	3964	5 L
	3968	1 L
CyMet™ III Diff CN free	3511.1000	1 L
CyMet™ Erma	3416.0500	500 ml
CyMet™ H20	3853.1000	1 L
CyMet™ KX CN Free	3425.0500	500 ml
CyMet™ Micro	3852.1000	1 L
CyMet™ Micro CN free	3863.1000	1 L micros
CyMet™ Mindray CN Free	3440.0500PE	500 ml
CyMet™ NR III	3484.1000PE	1 L
CyMet™ NR III CN Free	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
Cleaners		
Blanking Solution 1600/2000	3947	20 L
DetectoTerge™	3763	5 L
	3766	1 L
DetectoTerge™ BS	2970.0900PE	900 ml
ProClean™	3900	5 L
	3768.1000	1 L micros
ProClean™ Abacus	3432.5000	5 L
	3432.1000PE	1 L

J.T.Baker product list for CE marked products

ProClean™ CD	3902.0100PE	100 ml
ProClean™ Extra	3862.5000	5 L
	3867.1000PE	1 L micros
ProClean™ Plus	3901	100 ml
Rinse Mindray	3442.5000PE	5 L
Hematology Controls		
8-Parameter Control L/N/H	3427/3428/3429	2.5 ml
	3463/3464/3465	2.5 ml
8-Parameter Control L+N+H	3746	3 x 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 4xL	3466	4 x 2.5 ml
3-Diff Control 4xN	3467	4 x 2.5 ml
3-Diff Control 4xH	3468	4 x 2.5 ml
3-Diff Control extended L/N/H	3421/3422/3423	2.5 ml
BC-Diff 5 Control L/N/H	3613/3614/3615	3.0 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
Fixatives		
Cervix Spray Fixative	3869.1200	12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933.1000	1 L
10% v/v Buffered Formaldehyde (4% w/v)	3933.5000PC	5 L
10% v/v Buffered Formaldehyde (4% w/v)	3933.9010	10 L
10% v/v Buffered Formaldehyde (4% w/v)	3933.9020	20 L
Clearing agents		
UltraClear™	3905.2500PE	2.5 L
UltraClear™	3905.5000PE	5 L
UltraClear™	3905.9010PE	10 L
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
Eosin-Y Alcoholic	3800.2500PE	2.5 L
Giemsa	3856.1000	1 L
Giemsa	3856.2500	2.5 L
Hematoxylin er (Mayer)	3870.1000	1 L
Hematoxylin er (Mayer)	3870.2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873.1000	1 L
Hematoxylin Modified (Harris, Gill II)	3873.2500	2.5 L
May-Grünwald	3855.1000	1 L
May-Grünwald	3855.2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
Papanicolaou 2A	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
Papanicolaou 2B	3555.2500PE	2.5 L
Papanicolaou 3B	3556.1000PE	1 L
Papanicolaou 3B	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921.0500	500 ml
UltraKitt™	3921.0600	6 x 100 ml
Mounting medium High	3882.0500	500 ml
Mounting medium Low	3883.0500	500 ml
PBS and accessories		
PBS	3059	20 L
PBS	3059.9010PC	10 L

Appendix to
Conformity Declarations

Archem Diagnostic Systems



archem
DIAGNOSTICS

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Conformity also declared with all applicable harmonized standards, especially the following:

EN ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purpose.

EN ISO 14971: Medical devices — Application of risk management to medical devices.

EN ISO 17511: In vitro diagnostic medical devices — Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials.

EN ISO 18113-1: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements.

EN ISO 18113-2: In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for Professional use.

Other standards applied:

EN ISO 9001: Quality management systems

Note: Standards are used in this issue that is valid at date of issue of this conformity declaration.

Commercial Director

Erkan Uca

06.10.2022


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