

Declaration of Conformity

for Stains

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

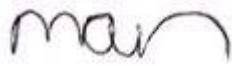
The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Stains
Legal Manufacturer: (Name on Label)	Pro-Lab Diagnostics 3 Bassendale Road Bromborough CH62 3QL UK
SRN:	GB-MF-000003833
Basic UDI-DI:	506047246Stains5R
Variants:	As per Appendix II (This document) – Product Listing/Schedule.
Intended Purpose:	Used in staining procedures for the identification and differentiation of microorganisms and cells.
IVDR Classification:	Class A [Rule 5].
Notified Body:	Not applicable for Class A devices.
CE Certificate:	Not applicable for Class A devices.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.

Name Mike Owen

Position Regulatory Affairs Manager

Signed



Date 2025-05-14

Place Pro-Lab Diagnostics

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements.

Appendix II – Product Listing/Schedule

Catalogue Number	Device Description	EMDN Code	UDI-DI
PL.375	Kovacs Reagent 100ml	W0104080209	50604724600048
PL.391-10	Spot Indole Reagent 10ml	W0104080209	50604724667850
PL.392	Calcofluor White Reagent 10ml	W0104030404	50604724600116
PL.393	10% Potassium Hydroxide Reagent 10ml	W0104030404	50604724600284
PL.7000/100	Crystal Violet 100ml	W0104010804	50604724600352
PL.7000/25	Crystal Violet 250ml	W0104010804	50604724600420
PL.7000	Crystal Violet 500ml	W0104010804	50604724600598
PL.7001	Crystal Violet 1000ml	W0104010804	50604724600666
PL.7002	Crystal Violet 2000ml	W0104010804	50604724600734
PL.7003/100	Grams Iodine 100ml	W0104010804	50604724600802
PL.7003/25	Grams Iodine 250ml	W0104010804	50604724600970
PL.7003	Grams Iodine 500ml	W0104010804	50604724601038
PL.7004	Grams Iodine 1000ml	W0104010804	50604724601106
PL.7005	Grams Iodine 2000ml	W0104010804	50604724601274
PL.7006/100	Grams Differentiator 100ml	W0104010804	50604724601342
PL.7006/25	Grams Differentiator 250ml	W0104010804	50604724601410
PL.7006	Grams Differentiator 500ml	W0104010804	50604724601588
PL.7007	Grams Differentiator 1000ml	W0104010804	50604724601656
PL.7008	Grams Differentiator 2000ml	W0104010804	50604724601724
PL.7009/100	Neutral Red 100ml	W0104010804	50604724601892
PL.7009/25	Neutral Red 250ml	W0104010804	50604724601960
PL.7009	Neutral Red 500ml	W0104010804	50604724602028
PL.7010	Neutral Red 1000ml	W0104010804	50604724602196
PL.7011	Neutral Red 2000ml	W0104010804	50604724602264
PL.7012/100	Safranin 100ml	W0104010804	50604724602332
PL.7012/25	Safranin 250ml	W0104010804	50604724602400
PL.7012	Safranin 500ml	W0104010804	50604724630748

PL.7013	Safranin 1000ml	W0104010804	50604724602646
PL.7014	Safranin 2000ml	W0104010804	50604724602714
PL.7015/100	Dilute Carbol Fuchsin 100ml	W0104010804	50604724602882
PL.7015/25	Dilute Carbol Fuchsin 250ml	W0104010804	50604724602950
PL.7015	Dilute Carbol Fuchsin 500ml	W0104010804	50604724603018
PL.7016	Dilute Carbol Fuchsin 1000ml	W0104010804	50604724603186
PL.7017	Dilute Carbol Fuchsin 2000ml	W0104010804	50604724603254
PL.7018/100	ZN Carbol Fuchsin 100ml	W0104010804	50604724603322
PL.7018/25	ZN Carbol Fuchsin 250ml	W0104010804	50604724603490
PL.7018	ZN Carbol Fuchsin 1000ml	W0104010804	50604724603568
PL.7019	ZN Carbol Fuchsin 1000ml	W0104010804	50604724603636
PL.7020	ZN Carbol Fuchsin 2000ml	W0104010804	50604724603704
PL.7021/25	Kinyoun Carbol Fuchsin 250ml	W0104010804	50602932502598
PL.7021	Kinyoun Carbol Fuchsin 500ml	W0104010804	50604724603872
PL.7022	Kinyoun Carbol Fuchsin 1000ml	W0104010804	50604724603940
PL.7024/100	Differentiator for ZN & Kinyoun Carbol Fuchsin 100ml	W0104010804	50604724604008
PL.7024/25	Differentiator for ZN & Kinyoun Carbol Fuchsin 250ml	W0104010804	50604724604176
PL.7025	Differentiator for ZN & Kinyoun Carbol Fuchsin 1000ml	W0104010804	50604724604244
PL.7026	Differentiator for ZN & Kinyoun Carbol Fuchsin 2000ml	W0104010804	50604724604312
PL.7027/100	Methylene Blue 100ml	W0104010804	50604724604558
PL.7027/25	Methylene Blue 250ml	W0104010804	50604724604626
PL.7027	Methylene Blue 500ml	W0104010804	50604724604794
PL.7028	Methylene Blue 1000ml	W0104010804	50604724604862
PL.7029	Methylene Blue 2000ml	W0104010804	50604724604930
PL.7030/100	Malachite Green 100ml	W0104010804	50604724605098
PL.7030/25	Malachite Green 250ml	W0104010804	50604724605166
PL.7030	Malachite Green 500ml	W0104010804	50604724605234
PL.7031	Malachite Green 1000ml	W0104010804	50604724605302
PL.7032	Malachite Green 2000ml	W0104010804	50604724605470
PL.7033/100	Auramine Phenol 100ml	W0104010804	50604724605548
PL.7033/25	Auramine Phenol 250ml	W0104010804	50604724605616
PL.7033	Auramine Phenol 500ml	W0104010804	50604724605784
PL.7034	Auramine Phenol 1000ml	W0104010804	50604724605852
PL.7035	Auramine Phenol 2000ml	W0104010804	50604724605920
PL.7036/100	Auramine Differentiator 500ml	W0104010804	50604724606088
PL.7036/25	Auramine Differentiator 500ml	W0104010804	50604724606156
PL.7036	Auramine Differentiator 500ml	W0104010804	50604724606224
PL.7037	Auramine Differentiator 1000ml	W0104010804	50604724606392
PL.7038	Auramine Differentiator 2000ml	W0104010804	50604724606460
PL.7039/100	Potassium Permanganate 100ml	W0104010804	50604724606538
PL.7039/25	Potassium Permanganate 250ml	W0104010804	50604724674612
PL.7039	Potassium Permanganate 500ml	W0104010804	50604724606606
PL.7040	Potassium Permanganate 1000ml	W0104010804	50604724606774
PL.7047	Leishmans Stain 500ml	W0104050102	50604724606842
PL.7050	Loefflers Methylene Blue 500ml	W0104010804	50604724606910

PL.7051	Loefflers Methylene Blue 1000ml	W0104010804	50604724607078
PL.7052	Lugols Iodine 500ml	W0104010804	50604724607146
PL.7053	Lugols Iodine 1000ml	W0104010804	50604724607214
PL.7053-2	Lugols Iodine 2000ml	W0104010804	50604724607382
PL.7054	Lactophenol Cotton Blue 500ml	W0104030404	50604724607450
PL.7055	Lactophenol Cotton Blue 1000ml	W0104030404	50604724607528
PL.7056	Iodine Acetone 500ml	W0104010804	50604724607696
PL.7057	Iodine Acetone 1000ml	W0104010804	50604724607764
PL.7058	Iodine Acetone 2000ml	W0104010804	50604724607832
PL.7059/100	Thiazine Red 100ml	W0104010804	50604724607900
PL.7059/25	Thiazine Red 250ml	W0104010804	50604724608068
PL.7059	Thiazine Red 500ml	W0104010804	50604724608136
PL.7060	Thiazine Red 1000ml	W0104010804	50604724608204
PL.7061	Polychrome Methylene Blue 250ml	W0104010804	50604724608372
PL.7061/5	Polychrome Methylene Blue 250ml	W0104010804	50604724608440
PL.7062	Cryptosporidium Stain 500ml	W0104050102	50604724608518
PL.7065	Differentiator 1 500ml	W0104050102	50604724608686
PL.7066	Polychrome Methylene Blue Fixative 250ml	W0104010804	50604724608754
PL.7066/5	Polychrome Methylene Blue Fixative 500ml	W0104010804	50604724608822
PL.7068	Differentiator 2 500ml	W0104050102	50604724608990
PL.7071	Cryptosporidium Counterstain 500ml	W0104050102	50604724609058
PL.7072	Cryptosporidium Fixative 500ml	W0104050102	50604724609126
PL.7073	Crystal Violet (Ammonium Oxalate) 500ml	W0104010804	50604724609294
PL.7074	Crystal Violet (Ammonium Oxalate) 1000ml	W0104010804	50604724609362
PL.7075	Crystal Violet (Ammonium Oxalate) 2000ml	W0104010804	50604724609430
PL.7076	Cryptosporidium Differentiator 500ml	W0104050102	50604724609508
PL.7077	Cryptosporidium Differentiator (3% Hydrochloric Acid)	W0104050102	50605550072016
PL.7100/CV	0.15% Crystal Violet 500ml	W0104010804	50604724610184
PL.7101/CV	0.15% Crystal Violet 1000ml	W0104010804	50604724610252
PL.7102/CV	0.15% Crystal Violet 2000ml	W0104010804	50604724610320
PL.7101	Basic Fuchsin/Neutral Red Counterstain 500ml	W0104010804	50605550022752
PL.7102	Basic Fuchsin/Neutral Red Counterstain 1000ml	W0104010804	50605550022820
PL.7103	Basic Fuchsin/Neutral Red Counterstain 2000ml	W0104010804	50605550022998
PL.7106	Grams Differentiator (Acetone/Propan-2-ol) 500ml	W0104010804	50604724610498
PL.7107	Grams Differentiator (Acetone/Propan-2-ol) 1000ml	W0104010804	50604724610566
PL.7108	Grams Differentiator (Acetone/Propan-2-ol) 2000ml	W0104010804	50604724610634
PL.7110	Sandifords Stain 500ml	W0104010804	50604724610702

PL.7111	Sandifords Stain 1000ml	W0104010804	50604724610870
PL.7112	Sandifords Stain 2000ml	W0104010804	50604724610948
PL.7113	Methyl Violet 500ml	W0104010804	50604724611006
PL.7114	Methyl Violet 1000ml	W0104010804	50604724611174
PL.7115	Methyl Violet 2000ml	W0104010804	50604724611242
PL.7116	Safranin/Neutral Red Counterstain 500ml	W0104010804	50604724611310
PL.7117	Safranin/Neutral Red Counterstain 1000ml	W0104010804	50604724611488
PL.7118	Safranin/Neutral Red Counterstain 2000ml	W0104010804	50604724611556
PL.7119	Sudan Black 0.5% 500ml	W0104010804	50604724611624
PL.7121	Waysons Stain 250ml	W0104010804	50604724611792
PL.7123	Fields Stain A 500ml	W0103010302	50604724611938
PL.7124	Fields Stain A 1000ml	W0103010302	50604724612096
PL.7125	Fields Stain B 500ml	W0103010302	50604724612164
PL.7126	Fields Stain B 1000ml	W0103010302	50604724612232
PL.7129	Alberts Stain 1 500ml	W0104010804	50604724612478
PL.7130	Alberts Stain 1 1000ml	W0104010804	50604724612546
PL.7131	Alberts Stain 1 2000ml	W0104010804	50604724612614
PL.7132	Alberts Stain 2 500ml	W0104010804	50604724612782
PL.7133	Alberts Stain 2 1000ml	W0104010804	50604724612850
PL.7134	Alberts Stain 2 2000ml	W0104010804	50604724612928
PL.7144	Auramine Differentiator (1% Hydrochloric Acid) 500ml	W0104010804	50605550071712
PL.7145	Auramine Differentiator (1% Hydrochloric Acid) 1000ml	W0104010804	50605550071880
PL.7146	Auramine Differentiator (1% Hydrochloric Acid) 2000ml	W0104010804	50605550071958
PL.7154	Lactofuchsin 100ml	W0104010804	50604724613086
PL.7206/25	Grams Differentiator (Acetone) 250ml	W0104010804	50604724613154
PL.7206	Grams Differentiator (Acetone) 500ml	W0104010804	50604724613222
PL.7207	Grams Differentiator (Acetone) 1000ml	W0104010804	50604724613390
PL.7208	Grams Differentiator (Acetone) 2000ml	W0104010804	50604724613468
PL.7306/25	Grams Differentiator (IMS) 250ml	W0104010804	50604724613536
PL.7306	Grams Differentiator (IMS) 500ml	W0104010804	50604724613604
PL.7307	Grams Differentiator (IMS) 1000ml	W0104010804	50604724613772
PL.7308	Grams Differentiator (IMS) 2000ml	W0104010804	50604724613840
PL.7406	Grams Differentiator (97% IMS/3% Acetone) 500ml	W0104010804	50604724613918
PL.7407	Grams Differentiator (97% IMS/3% Acetone) 1000ml	W0104010804	50604724614076
PL.7408	Grams Differentiator (97% IMS/3% Acetone) 2000ml	W0104010804	50604724614144
PL.8000	Crystal Violet concentrate 100ml	W0104010804	50604724614212
PL.8000/4	Crystal Violet concentrate 400ml	W0104010804	50604724614380
PL.8000/5	Crystal Violet concentrate 500ml	W0104010804	50604724614458
PL.8001	Grams Iodine concentrate 100ml	W0104010804	50604724614526
PL.8001/4	Grams Iodine concentrate 400ml	W0104010804	50604724614694

PL.8001/5	Grams Iodine concentrate 500ml	W0104010804	50604724614762
PL.8002	Neutral Red concentrate 100ml	W0104010804	50604724614830
PL.8002/4	Neutral Red concentrate 400ml	W0104010804	50604724614908
PL.8002/5	Neutral Red concentrate 500ml	W0104010804	50604724615066
PL.8003	Safranin concentrate 100ml	W0104010804	50604724615134
PL.8003/4	Safranin concentrate 400ml	W0104010804	50604724615202
PL.8003/5	Safranin concentrate 500ml	W0104010804	50604724615370
PL.8004	Dilute Carbol Fuchsin concentrate 100ml	W0104010804	50604724615448
PL.8004/4	Dilute Carbol Fuchsin concentrate 400ml	W0104010804	50604724615516
PL.8004/5	Dilute Carbol Fuchsin concentrate 500ml	W0104010804	50604724615684
PL.8005	ZN Carbol Fuchsin concentrate 100ml	W0104010804	50604724615752
PL.8005/4	ZN Carbol Fuchsin concentrate 400ml	W0104010804	50604724615820
PL.8005/5	ZN Carbol Fuchsin concentrate 500ml	W0104010804	50604724615998
PL.8006	Methylene Blue concentrate 100ml	W0104010804	50604724616056
PL.8006/4	Methylene Blue concentrate 400ml	W0104010804	50604724616124
PL.8006/5	Methylene Blue concentrate 500ml	W0104010804	50604724616292
PL.8007	Malachite Green concentrate 100ml	W0104010804	50604724616360
PL.8007/4	Malachite Green concentrate 400ml	W0104010804	50604724616438
PL.8007/5	Malachite Green concentrate 500ml	W0104010804	50604724616506
PL.8008	Auramine Phenol concentrate 100ml	W0104010804	50604724616674
PL.8008/4	Auramine Phenol concentrate 400ml	W0104010804	50604724616742
PL.8008/5	Auramine Phenol concentrate 500ml	W0104010804	50604724616810
PL.8009	Acridine Orange concentrate 100ml	W0104050102	50604724616988
PL.8009/4	Acridine Orange concentrate 400ml	W0104050102	50604724617114
PL.8009/5	Acridine Orange concentrate 500ml	W0104050102	50604724617282
PL.8010	Lugols Iodine concentrate 100ml	W0104010804	50604724617350
PL.8010/4	Lugols Iodine concentrate 400ml	W0104010804	50604724617428
PL.8010/5	Lugols Iodine concentrate 500ml	W0104010804	50604724617596
PL.8011	Methyl Violet concentrate 100ml	W0104010804	50604724617664
PL.8011/4	Methyl Violet concentrate 400ml	W0104010804	50604724617732
PL.8011/5	Methyl Violet concentrate 500ml	W0104010804	50604724617800
PL.8013	Potassium Permanganate concentrate 100ml	W0104010804	50604724617978
PL.8013/4	Potassium Permanganate concentrate 400ml	W0104010804	50604724618036
PL.8013/5	Potassium Permanganate concentrate 500ml	W0104010804	50604724618104
PL.8014	Basic Fuchsin concentrate 100ml	W0104010804	50604724618272
PL.8055/25	Grams Staining Kit (Safranin) 4x250ml	W0104010804	50604724618418
PL.8056/25	Grams Staining Kit (Neutral Red) 4x250ml	W0104010804	50604724618586
PL.8057/25	Grams Staining Kit (Dilute Carbol Fuchsin) 4x250ml	W0104010804	50604724618654
PL.8060/25	TB Staining Kit (Methylene Blue) 4x250ml	W0104010804	50604724618890
PL.8060	Cryptosporidium Staining Kit 7x500ml	W0104010804	50604724618722
PL.8061/25	TB Staining Kit (Malachite Green) 4x250ml	W0104010804	50604724618968

Version History

Version	Compiled by	Date	Description
1.0	M.Owen	2019 08 14	First issue
2.0	M.Owen	2020 01 24	Second issue
3.0	M.Owen	2020 10 15	Third issue
4.0	M.Owen	2022 05 12	Fourth issue
5.0	M.Owen	2025 05 13	Updated for Regulation (EU) 2017/746. Appendix II revised and updated.