

Declaration of Conformity

for Stains

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Names:	Stains
Manufacturer:	Pro-Lab Diagnostics, 3 Bassendale Road, Bromborough, CH62 3QL, UK.
Variants:	As per Appendix II – Product Listing/Schedule.
Intended Use:	Used in staining procedures for the identification and differentiation of microorganisms and cells.
Intended User:	Professional Use.
IVD Directive Category:	General
Notified Body:	n/a
IVD Directive Assessment route:	These products are <i>in vitro</i> medical devices as defined by Article 1 2(a) and 2(b) of Directive 98/79/EC. These products do not fall under Annex II list A or B in the Directive 98/79/EC and therefore are eligible for self-declaration of conformity under Annex III.
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Mike Owen

Position ISO Management System
Coordinator

Signed



Date 12/05/2022

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 his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I – Applicable Standards

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

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
PL.375	Kovacs Reagent 100ml	43587
PL.391-10	Spot Indole Reagent 10ml	43587
PL.392	Calcofluor White Reagent 10ml	43587
PL.393	10% Potassium Hydroxide Reagent 10ml	43587
PL.7000/100	Crystal Violet 100ml	43587
PL.7000/25	Crystal Violet 250ml	43587
PL.7000	Crystal Violet 500ml	43587
PL.7001	Crystal Violet 1000ml	43587
PL.7002	Crystal Violet 2000ml	43587
PL.7003/100	Grams Iodine 100ml	43587
PL.7003/25	Grams Iodine 250ml	43587
PL.7003	Grams Iodine 500ml	43587
PL.7004	Grams Iodine 1000ml	43587
PL.7005	Grams Iodine 2000ml	43587
PL.7006/100	Grams Differentiator 100ml	43606
PL.7006/25	Grams Differentiator 250ml	43606
PL.7006	Grams Differentiator 500ml	43606
PL.7007	Grams Differentiator 1000ml	43606
PL.7008	Grams Differentiator 2000ml	43606
PL.7009/100	Neutral Red 100ml	43587
PL.7009/25	Neutral Red 250ml	43587
PL.7009	Neutral Red 500ml	43587
PL.7010	Neutral Red 1000ml	43587
PL.7011	Neutral Red 2000ml	43587
PL.7012/100	Safranin 100ml	43587
PL.7012/25	Safranin 250ml	43587
PL.7012	Safranin 500ml	43587
PL.7013	Safranin 1000ml	43587
PL.7014	Safranin 2000ml	43587
PL.7015/100	Dilute Carbol Fuchsin 100ml	43587
PL.7015/25	Dilute Carbol Fuchsin 250ml	43587
PL.7015	Dilute Carbol Fuchsin 500ml	43587
PL.7016	Dilute Carbol Fuchsin 1000ml	43587
PL.7017	Dilute Carbol Fuchsin 2000ml	43587

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PL.7018/100	ZN Carbol Fuchsin 100ml	43587
PL.7018/25	ZN Carbol Fuchsin 250ml	43587
PL.7018	ZN Carbol Fuchsin 1000ml	43587
PL.7019	ZN Carbol Fuchsin 1000ml	43587
PL.7020	ZN Carbol Fuchsin 2000ml	43587
PL.7021	Kinyoun Carbol Fuchsin 500ml	43587
PL.7022	Kinyoun Carbol Fuchsin 500ml	43587
PL.7024/100	Differentiator for ZN & Kinyoun Carbol Fuchsin 100ml	43606
PL.7024/25	Differentiator for ZN & Kinyoun Carbol Fuchsin 250ml	43606
PL.7025	Differentiator for ZN & Kinyoun Carbol Fuchsin 1000ml	43606
PL.7026	Differentiator for ZN & Kinyoun Carbol Fuchsin 2000ml	43606
PL.7027/100	Methylene Blue 100ml	43587
PL.7027/25	Methylene Blue 250ml	43587
PL.7027	Methylene Blue 500ml	43587
PL.7028	Methylene Blue 1000ml	43587
PL.7029	Methylene Blue 2000ml	43587
PL.7030/100	Malachite Green 100ml	43587
PL.7030/25	Malachite Green 250ml	43587
PL.7030	Malachite Green 500ml	43587
PL.7031	Malachite Green 1000ml	43587
PL.7032	Malachite Green 2000ml	43587
PL.7033/100	Auramine Phenol 100ml	43587
PL.7033/25	Auramine Phenol 250ml	43587
PL.7033	Auramine Phenol 500ml	43587
PL.7034	Auramine Phenol 1000ml	43587
PL.7035	Auramine Phenol 2000ml	43587
PL.7036/100	Auramine Differentiator 100ml	43606
PL.7036/25	Auramine Differentiator 250ml	43606
PL.7036	Auramine Differentiator 500ml	43606
PL.7037	Auramine Differentiator 1000ml	43606
PL.7038	Auramine Differentiator 2000ml	43606
PL.7039	Potassium Permanganate 500ml	43587
PL.7040	Potassium Permanganate 1000ml	43587
PL.7047	Leishmans Stain 500ml	43587
PL.7050	Loefflers Methylene Blue 500ml	43587
PL.7051	Loefflers Methylene Blue 1000ml	43587
PL.7052	Lugols Iodine 500ml	43587
PL.7053	Lugols Iodine 1000ml	43587
PL.7053-2	Lugols Iodine 2000ml	43587
PL.7054	Lactophenol Cotton Blue 500ml	43587
PL.7055	Lactophenol Cotton Blue 1000ml	43587
PL.7056	Iodine Acetone 500ml	43587
PL.7057	Iodine Acetone 1000ml	43587
PL.7058	Iodine Acetone 2000ml	43587
PL.7059/100	Thiazine Red 100ml	43587
PL.7059/25	Thiazine Red 250ml	43587
PL.7059	Thiazine Red 500ml	43587
PL.7060	Thiazine Red 1000ml	43587
PL.7061	Polychrome Methylene Blue 250ml	43587
PL.7061/5	Polychrome Methylene Blue 250ml	43587
PL.7062	Cryptosporidium Stain 500ml	43587
PL.7065	Differentiator 1 500ml	43606

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PL.7066	Polychrome Methylene Blue Fixative 250ml	43587
PL.7066/5	Polychrome Methylene Blue Fixative 500ml	43587
PL.7068	Differentiator 2 500ml	43606
PL.7071	Cryptosporidium Counterstain 500ml	43587
PL.7072	Cryptosporidium Fixative 500ml	43587
PL.7073	Crystal Violet (Ammonium Oxalate) 500ml	43587
PL.7074	Crystal Violet (Ammonium Oxalate) 1000ml	43587
PL.7075	Crystal Violet (Ammonium Oxalate) 2000ml	43587
PL.7076	Cryptosporidium Differentiator 500ml	43606
PL.7077	Cryptosporidium Differentiator (3% Hydrochloric Acid)	43606
PL.7095	Auramine Rhodamine Phenol 500ml	43587
PL.7096	Auramine Rhodamine Phenol 1000ml	43587
PL.7097	Auramine Rhodamine Phenol 2000ml	43587
PL.7100/CV	0.15% Crystal Violet 500ml	43587
PL.7101/CV	0.15% Crystal Violet 1000ml	43587
PL.7102/CV	0.15% Crystal Violet 2000ml	43587
PL.7101	Basic Fuchsin/Neutral Red Counterstain 500ml	43587
PL.7102	Basic Fuchsin/Neutral Red Counterstain 1000ml	43587
PL.7103	Basic Fuchsin/Neutral Red Counterstain 2000ml	43587
PL.7106	Grams Differentiator (Acetone/Propan-2-ol) 500ml	43606
PL.7107	Grams Differentiator (Acetone/Propan-2-ol) 1000ml	43606
PL.7108	Grams Differentiator (Acetone/Propan-2-ol) 2000ml	43606
PL.7110	Sandifords Stain 500ml	43587
PL.7111	Sandifords Stain 1000ml	43587
PL.7112	Sandifords Stain 2000ml	43587
PL.7113	Methyl Violet 500ml	43587
PL.7114	Methyl Violet 1000ml	43587
PL.7115	Methyl Violet 2000ml	43587
PL.7116	Safranin/Neutral Red Counterstain 500ml	43587
PL.7117	Safranin/Neutral Red Counterstain 1000ml	43587
PL.7118	Safranin/Neutral Red Counterstain 2000ml	43587
PL.7119	Sudan Black 0.5% 500ml	43587
PL.7121	Waysons Stain 250ml	43587
PL.7123	Fields Stain A 500ml	43587
PL.7124	Fields Stain A 1000ml	43587
PL.7125	Fields Stain B 500ml	43587
PL.7126	Fields Stain B 1000ml	43587
PL.7129	Alberts Stain 1 500ml	43587
PL.7130	Alberts Stain 1 1000ml	43587
PL.7131	Alberts Stain 1 2000ml	43587
PL.7132	Alberts Stain 2 500ml	43587
PL.7133	Alberts Stain 2 1000ml	43587
PL.7134	Alberts Stain 2 2000ml	43587
PL.7144	Auramine Differentiator (1% Hydrochloric Acid) 500ml	43606
PL.7145	Auramine Differentiator (1% Hydrochloric Acid) 1000ml	43606
PL.7146	Auramine Differentiator (1% Hydrochloric Acid) 2000ml	43606
PL.7154	Lactofuchsin 100ml	43587
PL.7206/25	Grams Differentiator (Acetone) 250ml	43606
PL.7206	Grams Differentiator (Acetone) 500ml	43606
PL.7207	Grams Differentiator (Acetone) 1000ml	43606
PL.7208	Grams Differentiator (Acetone) 2000ml	43606
PL.7306/25	Grams Differentiator (IMS) 250ml	43606

PL.7306	Grams Differentiator (IMS) 500ml	43606
PL.7307	Grams Differentiator (IMS) 1000ml	43606
PL.7308	Grams Differentiator (IMS) 2000ml	43606
PL.7406	Grams Differentiator (97% IMS/3% Acetone) 500ml	43606
PL.7407	Grams Differentiator (97% IMS/3% Acetone) 1000ml	43606
PL.7408	Grams Differentiator (97% IMS/3% Acetone) 2000ml	43606
PL.8000	Crystal Violet concentrate 100ml	43587
PL.8000/4	Crystal Violet concentrate 400ml	43587
PL.8000/5	Crystal Violet concentrate 500ml	43587
PL.8001	Grams Iodine concentrate 100ml	43587
PL.8001/4	Grams Iodine concentrate 400ml	43587
PL.8001/5	Grams Iodine concentrate 500ml	43587
PL.8002	Neutral Red concentrate 100ml	43587
PL.8002/4	Neutral Red concentrate 400ml	43587
PL.8002/5	Neutral Red concentrate 500ml	43587
PL.8003	Safranin concentrate 100ml	43587
PL.8003/4	Safranin concentrate 400ml	43587
PL.8003/5	Safranin concentrate 500ml	43587
PL.8004	Dilute Carbol Fuchsin concentrate 100ml	43587
PL.8004/4	Dilute Carbol Fuchsin concentrate 400ml	43587
PL.8004/5	Dilute Carbol Fuchsin concentrate 500ml	43587
PL.8005	ZN Carbol Fuchsin concentrate 100ml	43587
PL.8005/4	ZN Carbol Fuchsin concentrate 400ml	43587
PL.8005/5	ZN Carbol Fuchsin concentrate 500ml	43587
PL.8006	Methylene Blue concentrate 100ml	43587
PL.8006/4	Methylene Blue concentrate 400ml	43587
PL.8006/5	Methylene Blue concentrate 500ml	43587
PL.8007	Malachite Green concentrate 100ml	43587
PL.8007/4	Malachite Green concentrate 400ml	43587
PL.8007/5	Malachite Green concentrate 500ml	43587
PL.8008	Auramine Phenol concentrate 100ml	43587
PL.8008/4	Auramine Phenol concentrate 400ml	43587
PL.8008/5	Auramine Phenol concentrate 500ml	43587
PL.8009	Acridine Orange concentrate 100ml	43587
PL.8009/4	Acridine Orange concentrate 400ml	43587
PL.8009/5	Acridine Orange concentrate 500ml	43587
PL.8010	Lugols Iodine concentrate 100ml	43587
PL.8010/4	Lugols Iodine concentrate 400ml	43587
PL.8010/5	Lugols Iodine concentrate 500ml	43587
PL.8011	Methyl Violet concentrate 100ml	43587
PL.8011/4	Methyl Violet concentrate 400ml	43587
PL.8011/5	Methyl Violet concentrate 500ml	43587
PL.8013	Potassium Permanganate concentrate 100ml	43587
PL.8013/4	Potassium Permanganate concentrate 400ml	43587
PL.8013/5	Potassium Permanganate concentrate 500ml	43587
PL.8014	Basic Fuchsin concentrate 100ml	43587
PL.8055/25	Grams Staining Kit (Safranin) 4x250ml	43587
PL.8055/100	Grams Staining Kit (Safranin) 4x100ml	43587
PL.8056/25	Grams Staining Kit (Neutral Red) 4x250ml	43587
PL.8056/100	Grams Staining Kit (Neutral Red) 4x100ml	43587
PL.8057/25	Grams Staining Kit (Dilute Carbol Fuchsin) 4x250ml	43587
PL.8057/100	Grams Staining Kit (Dilute Carbol Fuchsin) 4x100ml	43587

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PL.8060/25	TB Staining Kit (Methylene Blue) 4x250ml	43587
PL.8060/100	TB Staining Kit (Methylene Blue) 4x100ml	43587
PL.8060	Cryptosporidium Staining Kit 7x500ml	43587
PL.8061/25	TB Staining Kit (Malachite Green) 4x250ml	43587
PL.8061/100	TB Staining Kit (Malachite Green) 4x250ml	43587
PL.8062/25	Auramine-Thiazine Kit 3x250ml	43587
PL.8063/25	TB Staining Kit (Fluorescent) 3x250ml	43587
PL.8065/25	TB Staining Kit Kinyoun (Cold) 3x250ml	43587

Version History

Version	Compiled by	Date	Description
3.0	Mike Owen	15/10/2020	Third issue
4.0	Mike Owen	12/05/2022	Fourth issue