

## Declaration of Conformity

for Gram Stains

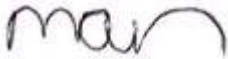
### Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

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.

|                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General Product Name:</b>               | Crystal Violet<br>Crystal Violet (Ammonium Oxalate)<br>Crystal Violet 0.15%<br>Methyl Violet<br>Grams Iodine<br>Lugols Iodine<br>Grams Differentiator<br>Grams Differentiator (Acetone/Propan-2-ol)<br>Grams Differentiator (Acetone)<br>Grams Differentiator (IMS)<br>Grams Differentiator (97% IMS/3% Acetone)<br>Iodine Acetone<br>Safranin<br>Neutral Red<br>Dilute Carbol Fuchsin<br>Basic Fuchsin/Neutral Red<br>Safranin/Neutral Red<br>Sandifords Stain<br>Crystal Violet Concentrate<br>Methyl Violet Concentrate<br>Grams Iodine Concentrate<br>Lugols Iodine Concentrate<br>Safranin Concentrate<br>Neutral Red Concentrate<br>Dilute Carbol Fuchsin Concentrate |
| <b>Legal Manufacturer: (Name on Label)</b> | Pro-Lab Diagnostics<br>3 Bassendale Road<br>Bromborough<br>CH62 3QL<br>UK                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>SRN:</b>                                | GB-MF-000003833                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Basic UDI-DI:</b>                       | 506047246GramStainsFA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Variants:</b>                           | As per Appendix II (This document) – Product Listing/Schedule.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Intended Purpose:</b>                   | For use in the Gram staining method for the rapid differentiation of Gram-positive and Gram-negative bacteria in prepared slides from clinical specimens.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

|                                          |                                                                                                                                                                    |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>IVDR Classification:</b>              | Class A [Rule 5].                                                                                                                                                  |
| <b>Notified Body:</b>                    | Not applicable for Class A devices.                                                                                                                                |
| <b>CE Certificate:</b>                   | Not applicable for Class A devices.                                                                                                                                |
| <b>EU Authorised Representative:</b>     | Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.                                                                 |
| <b>EU Authorised Representative SRN:</b> | MT-AR-000000234                                                                                                                                                    |
| <b>IVDR Assessment Route:</b>            | 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** 2026-05-07 **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):

| <b>Standard/CS/Document Name</b> | <b>Description</b>                                                                                                                                |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| 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**

| <b>Catalogue Number</b> | <b>Device Description</b>                  | <b>EMDN Code</b> | <b>UDI-DI</b>  |
|-------------------------|--------------------------------------------|------------------|----------------|
| 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.7052                 | Lugols Iodine (500ml)                      | W0104010804      | 50604724607146 |
| PL.7053                 | Lugols Iodine (1000ml)                     | W0104010804      | 50604724607214 |
| PL.7053-2               | Lugols Iodine (2000ml)                     | W0104010804      | 50604724607382 |
| PL.7056                 | Iodine Acetone (500ml)                     | W0104010804      | 50604724607696 |
| PL.7057                 | Iodine Acetone (1000ml)                    | W0104010804      | 50604724607764 |
| PL.7058                 | Iodine Acetone (2000ml)                    | W0104010804      | 50604724607832 |
| 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.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 (500ml)          | W0104010804      | 50605550022752 |

|            |                                                     |             |                |
|------------|-----------------------------------------------------|-------------|----------------|
| PL.7102    | Basic Fuchsin/Neutral Red (1000ml)                  | W0104010804 | 50605550022820 |
| PL.7103    | Basic Fuchsin/Neutral Red (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 (500ml)                        | W0104010804 | 50604724611310 |
| PL.7117    | Safranin/Neutral Red (1000ml)                       | W0104010804 | 50604724611488 |
| PL.7118    | Safranin/Neutral Red (2000ml)                       | W0104010804 | 50604724611556 |
| 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.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 |

**Version History**

| Version | Compiled by | Date       | Description  |
|---------|-------------|------------|--------------|
| 1.0     | M.Owen      | 2026 05 07 | First issue. |