

# Declaration of Conformity

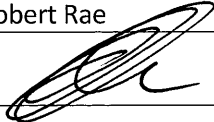
## for Prolex™ Streptococci Latex Kits

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.

|  |   |
|--|---|
| <b>General Product Names:</b>          | Prolex™ Streptococci Latex Kits   |
| <b>Manufacturer:</b>                   | Pro-Lab Diagnostics, 20 Mural Street, Unit #4, Richmond Hill, Ontario, Canada, L4B 1K3.   |
| <b>Variants:</b>                       | As per Appendix II – Product Listing/Schedule.  |
| <b>Intended Use:</b>                   | Serological identification of <i>Streptococci</i> Groups A, B, C, D, F and G.   |
| <b>Intended User:</b>                  | Professional Use  |
| <b>IVD Directive Category:</b>         | General   |
| <b>Notified Body:</b>                  | n/a   |
| <b>IVD Directive Assessment route:</b> | These products are <i>in vitro</i> medical devices as defined by Article 1 2(a) and 2(b) of Directive 98/79/EC.<br>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. |
| <b>EU Authorised Representative:</b>   | Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Floor, Tower Street, Swatar BKR 4013 Malta   |

Name Robert Rae Position President

Signed  Date 2020 01 21

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.030                | Prolex™ Streptococcal Grouping Latex Kit                           | 43586     |
| PL.031                | Prolex™ Streptococcal Grouping Reagent Latex Suspension Group A    | 43586     |
| PL.032                | Prolex™ Streptococcal Grouping Reagent Latex Suspension Group B    | 43586     |
| PL.033                | Prolex™ Streptococcal Grouping Reagent Latex Suspension Group C    | 43586     |
| PL.034                | Prolex™ Streptococcal Grouping Reagent Latex Suspension Group D    | 43586     |
| PL.035                | Prolex™ Streptococcal Grouping Reagent Latex Suspension Group F    | 43586     |
| PL.036                | Prolex™ Streptococcal Grouping Reagent Latex Suspension Group G    | 43586     |
| PL.037                | Prolex™ Streptococcal Grouping Reagent Extraction Reagent 1        | 43586     |
| PL.038                | Prolex™ Streptococcal Grouping Reagent Extraction Reagent 2        | 43586     |
| PL.039                | Prolex™ Streptococcal Grouping Reagent Extraction Reagent 3        | 43586     |
| PL.040                | Prolex™ Streptococcal Grouping Reagent Polyvalent Positive Control | 43586     |
| PL.041                | Prolex™ Streptococcal-Select Grouping Latex Kit                    | 43586     |
| PL.046                | Prolex™ Extraction Reagent Set                                     | 43586     |

**Version History**

| Version | Compiled by      | Date       | Description |
|---------|------------------|------------|-------------|
| 1.0     | M. Owen / L. Gin | 2020 01 16 | First issue |