Declaration of Conformity

for Prolex™ Staphylococci 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.

General Product Names:	Prolex™ Staphylococci Latex Kit
Manufacturer:	Pro-Lab Diagnostics, 20 Mural Street, Unit #4, Richmond Hill, Ontario, Canada, L4B 1K3.
Variants:	As per Appendix II – Product Listing/Schedule.
Intended Use:	Presumptive identification of *S. aureus.*
Intended User:	Professional Use
IVD Directive Category:	General
Notified Body:	n/a
IVD Directive Assessment route:	These products are *in vitro* 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, 2nd 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.080B	Prolex™ Staph Latex Kit	51659
PL.081B	Prolex™ Staph Latex Kit	51659
PL.1080	Prolex™ Staph Xtra Latex Kit	51659
PL.1081	Prolex™ Staph Xtra Latex Kit	51659

Version History

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