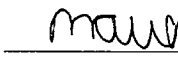
Declaration of Conformity
For Coagulase Plasma

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:	Coagulase Plasma
Manufacturer:	Pro-Lab Diagnostics, 3 Bassendale Road, Bromborough, CH62 3QL, UK.
Variants:	As per Appendix II – Product Listing/Schedule.
Intended Use:	Qualitative detection of the coagulase enzyme produced by *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 Mike Owen **Position** ISO Management System Coordinator

Signed  **Date** 14/10/2019

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.850	Rabbit Coagulase Plasma (10x3ml)	42737
PL.850-10	Rabbit Coagulase Plasma (10ml)	42737
PL.850-20	Rabbit Coagulase Plasma (20ml)	42737
PL.850-30	Rabbit Coagulase Plasma (30ml)	42737

Version History

Version	Compiled by	Date	Description
1.0	Mike Owen	14/08/2019	First issue