



Declaration of Conformity

This United Kingdom Declaration of Conformity is issued under the sole responsibility of the manufacturer.

| MANUFACTURER | | |
|---|---|---|
| Name of Company | Address | SRN |
| Bio/Data Corporation | 155 Gibraltar Road, Horsham, PA 19044 U.S.A. | US-MF-000026991 |
| UK RESPONSIBLE PERSON | | |
| Name of Company | Address | Telephone/email |
| Alpha Laboratories Ltd | 40 Parham Drive, Eastleigh, Hampshire SO50 4NU UNITED KINGDOM | +44 2380 483000 – phone quality@alphalabs.co.uk |
| PRODUCT IDENTIFICATION | | |
| Product / Trade Name | Product Code / Catalog Number | Basic UDI-DI |
| AggRecetin 1.0-1.5 | 100970 | ++G0561009704A |
| Intended Purpose See Instructions for Use | | Photo See website www.biodatacorp.com |
| AggRecetin (Ristocetin) Reagent is intended for use in performing routine Ristocetin-Induced Platelet Aggregation (RIPA) testing on Platelet-Rich Plasma (PRP) samples to assess platelet function. | | |
| IVDR RISK CLASS / COMMON SPECIFICATIONS | | |
| Device Classification | | Common Specifications |
| Class | General IVD (Self Certified) | Sections 1-5 (as modified by Part III of Schedule 2A to the UK MDR 2002) |
| Rule | Part IV of the UK MDR 2002, Annex III | |

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www.biodatacorp.com e-mail: customer.service@biodatacorp.com
An ISO 13485 Registered Company

Bio/Data Corporation, the Manufacturer, declares that the above-mentioned product meets the provision of the following UK legislation:

Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

Conformity Statement:

Bio/Data Corporation declares that the above-mentioned products meet the provision of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) for In Vitro Diagnostic Medical Devices.

Notified Body (NB) Identification, conformity assessment procedure performed and identification if the certificate or certificates issued:

Not applicable. The conformity assessment procedure for General IVD (non-Annex II) Devices should be carried out, as a general rule, under the sole responsibility of manufacturers, since such devices pose a low risk to patients.

(Self-Declaration)

COMPANY REPRESENTATIVE: William M. Trolio

SIGNATURE: _____



TITLE/FUNCTION: Director of Quality Assurance & Regulatory Affairs for Bio/Data Corporation

PLACE: Bio/Data Corporation, Horsham, PA. 19044 U.S.A.

DATE: 7 April 2025