



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		Photo
See Instructions for Use		See website www.biodatacorp.com
AggRecetin reagent is the required reagent, used in combination with other IVD components, to perform a Ristocetin Cofactor Activity test on Platelet Poor Plasma.		
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	

155 Gibraltar Road, Horsham, PA 19044 U.S.A.
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 Fax Worldwide: (215) 443-8820
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: 1 April 2023