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**
Lyophilized Platelets 10mL	101258	++G0561012583Q
Intended Purpose **See Instructions for Use**		**Photo** **See website www.biodatacorp.com**
Lyophilized Platelets are a standardized and fixed suspension of human platelets routinely used as a component of a Ristocetin Cofactor Assay Activity Test.		

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.
Worldwide: (215) 441-4000 U.S.A.: (800) 257-3282
Fax Worldwide: (215) 443-8820
www.biodatacorp.com e-mail: customer.service@biodatacorp.com
An ISO 13485 Registered Company

BIO/DATA CORPORATION
An ISO 13485 Registered Company

www.biodatacorp.com
customer.service@biodatacorp.com

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