



## 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 <a href="mailto:quality@alphalabs.co.uk">quality@alphalabs.co.uk</a>
PRODUCT IDENTIFICATION		
Product / Trade Name	Product Code / Catalog Number	Basic UDI-DI
Lyophilized Platelets 3 x 4 mL	101595	++G0561015954D
Intended Purpose	Photo	
See Instructions for Use	See website <a href="http://www.biodatacorp.com">www.biodatacorp.com</a>	
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	

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[www.biodatacorp.com](http://www.biodatacorp.com) e-mail: [customer.service@biodatacorp.com](mailto: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