



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
Platelet Aggregation Profiler, Model PAP-8E	106075 Domestic 106077 International	*+G0561060751 *+G0561060771
Intended Purpose		Photo
See Instructions for Use		See website www.biodatacorp.com
<p>The Platelet Aggregation Profiler, Model PAP-8E is a semi-automated Light Transmission Aggregometer (LTA) used to observe and record Routine and Special Aggregation Testing, and Ristocetin CoFactor Activity.</p> <p>Routine and Special Aggregation Testing involves the introduction of a common agonist into a Platelet Rich Plasma (PRP) sample. The PAP-8E measures the change in optical density according to the method described by Dr. GVR Born. The semi-quantitative results are used to differentiate functional status and abnormalities as an aid to physician interpretation and diagnosis.</p> <p>Ristocetin CoFactor Activity involves the addition of Ristocetin into a mixture of Lyophilized Platelets and Platelet Poor Plasma (PPP). The PAP-8E measures the change in optical density according to the method described by Dr. Harvey Weiss.</p> <p>Platelet Function Testing is a useful tool for laboratory evaluation of Inherited or Acquired Hemostatic Abnormalities, Clinical Investigation of Bleeding or Thrombotic States, assessment of Anti-Platelet Therapy, Pharmacological Studies, and Research Protocols.</p>		

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	

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