EU Declaration of Conformity

This 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 USA	US-MF-000026991

AUTHORIZED REPRESENTATIVE

Name of Company	Address	SRN	Telephone / Email
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PRODUCT IDENTIFICATION

Product / Trade Name	Product Code / Catalog Number	Basic UDI-DI	EMDN Code
Platelet Aggregation Profiler, Model PAP-8E	106075 Domestic 106077 International	*+G0561060751 *+G0561060771	W0202029099

Intended Purpose	Photo
See Instructions For Use	**See website www.biodatacorp.com**

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.

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.

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.

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.

IVDR RISK CLASS / COMMON SPECIFICATIONS

Device Classification	Common Specifications
Class A (non-sterile)	None currently published for this device type.
Rule 5(b) per Annex VIII of Regulation (EU) 2017/746	

APPLICABLE LEGISLATION

Bio/Data Corporation, the Manufacturer, declares that the above-mentioned product meets the provisions of the following European Union legislation:

- Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)
- Directive 2011/65/EU and Amendment (EU) 2015/863 on the Restriction of Hazardous Substances (RoHS)
- Directive 2014/30/EU on Electromagnetic Compatibility (EMC)

Compliance has been demonstrated with the applicable harmonized standards, including:

- EN ISO 13485:2016 + A11:2021 – Medical Devices – Quality Management Systems
- EN 61326-2-6:2020 – Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements for IVD Equipment

For accompanying accessories such as the All-In-One Computer and Picus Pipette, please refer to the respective manufacturers for their individual Declarations of Conformity (DoC).

CONFORMITY STATEMENT

Bio/Data Corporation confirms that the device covered by this Declaration of Conformity is in conformity with Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) and, where applicable, with any other relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

Conformity Assessment Route: Annex II and Annex III of Regulation (EU) 2017/746.

NOTIFIED BODY (NB) INVOLVEMENT

Not applicable. The conformity assessment procedure for Class A (non-sterile) devices is carried out under the sole responsibility of the manufacturer, as such devices are considered to present a low risk to patients.

This device has been self-declared in accordance with Annex II and Annex III of Regulation (EU) 2017/746.

QUALITY ASSURANCE / REGULATORY APPROVAL

Signature: 

Date: 13 November 2025

William M. Trolio
Director of Quality Assurance & Regulatory Affairs
Bio/Data Corporation
Horsham, PA 19044 USA