Declaration of Conformity

This European 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

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/email**
mdi Europa GmbH	Langenhagener Str. 71 D-30855 Langenhagen GERMANY	DE-AR-000006218	+49-511-3908 9531 – phone info@mdi-europa.com

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 **See Instructions For Use**		**Photo** **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	No relevant common specifications have been published yet.
Rule	5b per Annex VIII of IVDR 2017/746	

Bio/Data Corporation, the Manufacturer, declares that the above-mentioned product meets the provision of the following EU legislation:

In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746
RoHS Directive 2011/65/EU, 2015/863/EU, and subsequent amendments
Electromagnetic Compatibility Directive 2014/30/EU and subsequent amendments

For the PAP-8E Platelet Aggregometer accompanying accessories, such as the All-In-One Computer and Picus Pipette, please refer to the respective manufacturers for their Declaration of Conformity (DOC).

Conformity Statement:

Bio/Data Corporation confirms that the device covered by this declaration is in conformity with the (EU) IVDR 2017/746 Regulation and, if applicable, with any other relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Notified Body (NB) Identification, conformity assessment procedure performed and identification if the certificate or certificates issued:

Not applicable. The conformity assessment procedure for Class A 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 USA **DATE:** 4 February 2025