



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
Name of Company	Address	SRN	Telephone/email
Mdi Europa	Langenhagener Str. 71 30855 Langenhagen GERMANY	DE-AR-000006218	+49-511-3908 9531 – phone info@mdi-europa.com
Product / Trade Name	Product Code / Catalog Number	Basic UDI-DI	
Platelet Aggregation Profiler, Model PAP-8E	106077 International	++G0561060774M	
Intended Purpose See 106221 Operating Manual			
<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>			

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 2015/863/EU

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. Trolie

SIGNATURE:



TITLE/FUNCTION: Director of Quality Assurance & Regulatory Affairs for Bio/Data Corporation

PLACE: Bio/Data Corporation, Horsham, PA. 19044 U.S.A.

DATE: 3 February 2023