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**
Epinephrine	101311		++G05610131133
Intended Purpose **See Instructions for Use**			**Photo** **See website www.biodatacorp.com**
Epinephrine (adrenalin) reagent is for routine use in platelet studies for the evaluation of hypersensitivity of platelets in Platelet Rich Plasma and evaluation of platelet responses to a weak agonist.			
IVDR RISK CLASS / COMMON SPECIFICATIONS			
Device Classification		**Common Specifications**	
Class	A non-sterile	No relevant common specifications have been published yet.	
Rule	5a per Annex VIII of IVDR 2017/746		

155 Gibraltar Road, Horsham, PA 19044 U.S.A.
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Fax Worldwide: (215) 443-8820
www.biodatacorp.com e-mail: 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 EU legislation:

In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746

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 U.S.A. **DATE:** 1 April 2023