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 REPRESENTATIVES			
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**
Siliconized Macro Test Tubes	100336	++G0561003363C
Intended Purpose **See Instructions for Use**		**Photo** **See website www.biodatacorp.com**
Macro Test Tubes are single use, flat bottom, silicone coated test tubes used as test cuvettes for blank and test samples for platelet function studies. Disposable Macro Test Tubes are for use with the PAP-4 Series Platelet Aggregation Profilers using Macro Stir Bars.		

IVDR RISK CLASS / COMMON SPECIFICATIONS		
Device Classification		**Common Specifications**
Class	A non-sterile	No relevant common specifications have been published yet.
Rule	5c per Annex VIII of IVDR 2017/746	

155 Gibraltar Road, Horsham, PA 19044 U.S.A.
Worldwide: (215) 441-4000 U.S.A.: (800) 257-3282
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