



## 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 U.S.A.	US-MF-000026991	
AUTHORIZED REPRESENTATIVES			
Name of Company	Address	SRN	Telephone/email
mdi Europa GmbH	Langenhagener Str. 71 30855 Langenhagen GERMANY	DE-AR-000006218	+49-511-3908 9531 – phone <a href="mailto:info@mdi-europa.com">info@mdi-europa.com</a>
PRODUCT IDENTIFICATION			
Product / Trade Name	Product Code / Catalog Number	Basic UDI-DI	
Siliconized Macro Test Tubes	100336	++G0561003363C	
Intended Purpose		Photo	
See Instructions For Use		See website <a href="http://www.biodatacorp.com">www.biodatacorp.com</a>	
For use with the PAP-4 series aggregometer.			
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		

**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: 3 February 2023