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**
Siliconized Micro Test Tubes	101521		++G0561015213G
Intended Purpose **See Instructions For Use**			**Photo** **See website www.biodatacorp.com**
Micro 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 Micro Test Tubes are for use with the PAP-8E Platelet Aggregation Profiler or PAP-4 Series Platelet Aggregation Profiler using Micro Volume Adapters.			
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.
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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