



## EU 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 USA	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 <a href="mailto:info@mdi-europa.com">info@mdi-europa.com</a>
PRODUCT IDENTIFICATION			
Product / Trade Name	Product Code / Catalog Number	Basic UDI-DI	EMDN Code
Micro Test Tubes	101521	++G0561015213G	W0503010102
Intended Purpose		Photo	
<b>See Instructions for Use</b>		<b>See website <a href="http://www.biodatacorp.com">www.biodatacorp.com</a></b>	
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)	None currently published for this device type.		
Rule 5(a) per Annex VIII of Regulation (EU) 2017/746			

**An ISO 13485 Registered Company**

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## APPLICABLE LEGISLATION

Bio/Data Corporation, the Manufacturer, declares that the above-mentioned product meets the provisions of the following European Union legislation:

- Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)

Compliance has been demonstrated with the applicable harmonized standards, including:

- EN ISO 13485:2016 + A11:2021 – Medical Devices – Quality Management Systems
- EN ISO 14971:2019 + A11:2021 – Medical Devices – Application of Risk Management to Medical Devices

## CONFORMITY STATEMENT

Bio/Data Corporation confirms that the device covered by this Declaration of Conformity is in conformity with Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR) and, where applicable, with any other relevant Union legislation that provides for the issuing of an EU Declaration of Conformity.

Conformity Assessment Route: Annex II and Annex III of Regulation (EU) 2017/746.

## NOTIFIED BODY (NB) INVOLVEMENT

Not applicable. The conformity assessment procedure for Class A (non-sterile) devices is carried out under the sole responsibility of the manufacturer, as such devices are considered to present a low risk to patients.

This device has been self-declared in accordance with Annex II and Annex III of Regulation (EU) 2017/746.

## QUALITY ASSURANCE / REGULATORY APPROVAL

Signature: \_\_\_\_\_



Date: 30 March 2026

William M. Trolio  
Director of Quality Assurance & Regulatory Affairs  
Bio/Data Corporation  
Horsham, PA 19044 USA