



## 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<br>Horsham, PA 19044 USA             | US-MF-000026991                                                          |                                                                                           |
| AUTHORIZED REPRESENTATIVE                                                                                                                                                                                                                                                                                                 |                                                         |                                                                          |                                                                                           |
| Name of Company                                                                                                                                                                                                                                                                                                           | Address                                                 | SRN                                                                      | Telephone / Email                                                                         |
| mdi Europa GmbH                                                                                                                                                                                                                                                                                                           | Langenhagener Str. 71<br>D-30855 Langenhagen<br>GERMANY | DE-AR-000006218                                                          | +49-511-3908 9531 – phone<br><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                                                                    |                                                                                           |
| See Instructions for Use                                                                                                                                                                                                                                                                                                  |                                                         | See website <a href="http://www.biodatacorp.com">www.biodatacorp.com</a> |                                                                                           |
| 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(b) 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 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: 13 November 2025

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