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 info@mdi-europa.com

PRODUCT IDENTIFICATION			
Product / Trade Name	**Product Code / Catalog Number**	**Basic UDI-DI**	**EMDN Code**
Lyophilized Platelets	101258	++G0561012583Q	W01030199 W0103010605
Intended Purpose		**Photo**	
See Instructions for Use		See website www.biodatacorp.com	
Lyophilized Platelets are a standardized and fixed suspension of human platelets routinely used as a component of a Ristocetin Cofactor Assay Activity Test.			

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	

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: 13 November 2025

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