



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		
vW Normal Reference Plasma	101269	++G0561012693V	W01030199		
Intended Purpose		Photo			
See Instructions for Use		See website www.biodatacorp.com			
vW Normal Reference Plasma is prepared from a pool of citrated normal infection negative human plasma which has been lyophilized. It is used to construct a standard curve for the Ristocetin Cofactor Activity Assay 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					

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: 13 November 2025

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