



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
TRIS Buffered Saline	100991	++G0561009914J	W01030199
Intended Purpose		Photo	
See Instructions for Use		See website www.biodatacorp.com	
TRIS Buffered Saline is routinely used for the reconstitution and dilution of reagents and samples tested for platelet aggregation, Ristocetin Cofactor Activity Assays or other laboratory studies.			
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

155 Gibraltar Road, Horsham, PA 19044 USA

+1 215-441-4000 Worldwide / 1-800-257-3282 USA / +1 215-443-8820 Fax Worldwide

Website: www.biodatacorp.com Email: customer.service@biodatacorp.com

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