



Declaration of Conformity

This European 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 U.S.A.	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
Lyophilized Platelets 3 x 4 mL		101595		++G0561015954D
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	No relevant common specifications have been published yet.		
Rule	5a per Annex VIII of IVDR 2017/746			

Bio/Data Corporation, the Manufacturer, declares that the above-mentioned product meets the provision of the following EU legislation:

In Vitro Diagnostic Medical Device Regulation (IVDR) (EU) 2017/746

Conformity Statement:

Bio/Data Corporation confirms that the device covered by this declaration is in conformity with the (EU) IVDR 2017/746 Regulation and, if applicable, with any other relevant Union Legislation that provides for the issuing of an EU Declaration of Conformity.

Notified Body (NB) Identification, conformity assessment procedure performed and identification if the certificate or certificates issued:

Not applicable. The conformity assessment procedure for Class A Devices should be carried out, as a general rule, under the sole responsibility of manufacturers, since such devices pose a low risk to patients. (Self-Declaration)

COMPANY REPRESENTATIVE: William M. Trolio

SIGNATURE: _____



TITLE/FUNCTION: Director of Quality Assurance & Regulatory Affairs for Bio/Data Corporation

PLACE: Bio/Data Corporation, Horsham, PA. 19044 U.S.A.

DATE: 1 April 2023