



## Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

<b>MANUFACTURER</b>			
<b>Name of Company</b>		<b>Address</b>	<b>SRN</b>
Bio/Data Corporation		155 Gibraltar Road, Horsham, PA 19044 U.S.A.	US-MF-000026991
<b>AUTHORIZED REPRESENTATIVE</b>			
<b>Name of Company</b>	<b>Address</b>	<b>SRN</b>	<b>Telephone/email</b>
mdi Europa GmbH	Langenhagener Str. 71 D-30855 Langenhagen GERMANY	DE-AR-000006218	+49-511-3908 9531 – phone <a href="mailto:info@mdi-europa.com">info@mdi-europa.com</a>
<b>PRODUCT IDENTIFICATION</b>			
<b>Product / Trade Name</b>		<b>Product Code / Catalog Number</b>	<b>Basic UDI-DI</b>
Lyophilized Platelets 10mL		101258	++G0561012583Q
<b>Intended Purpose</b>			<b>Photo</b>
See Instructions for Use			See website <a href="http://www.biodatacorp.com">www.biodatacorp.com</a>
Lyophilized Platelets are a standardized and fixed suspension of human platelets routinely used as a component of a Ristocetin Cofactor Assay Activity Test.			
<b>IVDR RISK CLASS / COMMON SPECIFICATIONS</b>			
<b>Device Classification</b>		<b>Common Specifications</b>	
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