



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	Langenhagener Str. 71 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	
Lupus Anticoagulant Confirmation Reagent	102516	++G0561025163W	
Intended Purpose		Photo	
See Instructions for Use		See website www.biodatacorp.com	
Lupus Anticoagulant Confirmation Reagent is the third test component, phosphatidyl platelet phospholipid solution, used after and with other IVD reagents to confirm the prior three previous tests correctly flagged a sample as one containing the lupus anticoagulant.			
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

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 An ISO 13485 Registered Company

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: _____

A handwritten signature in black ink, appearing to read 'W. Trolio', written over a horizontal line.

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

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

DATE: 3 February 2023