



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	
Lupus Anticoagulant Confirmation Reagent		102516	++G0561025163W	
Intended Purpose			Photo	
See Instructions for Use			See website www.biodatacorp.com	
Lupus Anticoagulant Confirmation Reagent™ is a platelet phospholipid solution used to perform the platelet neutralization procedure. Use of the LA-CR test kit confirms that previous laboratory results have correctly flagged a sample as 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			

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 An ISO 13485 Registered Company



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customer.service@biodatacorp.com

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: _____

A handwritten signature in blue ink, appearing to read "W. Trolio", is 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: 1 April 2023