



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 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
LTA Check Kit		107117	*+G0561071170
Intended Purpose			Photo
See Instructions for Use			See website www.biodatacorp.com
Performance Verification, Aggregation: The LTA Check✓ Kit is used to verify Light Transmission Aggregometer system performance. Operator Training and Performance Verification: The LTA Check✓ Kit may be used to train operators to properly perform platelet aggregation and to document operator proficiency.			
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: _____

A handwritten signature in black ink, appearing to read 'W. Trolio', is written over a horizontal line. The signature is somewhat stylized and includes a circular flourish above the first part of the name.

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

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

DATE: 24/3/2023