



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
Macro Stir Bars		105977	++G0561059775T
Intended Purpose			Photo
See Instructions for Use			See website www.biodatacorp.com
Macro Stir Bars are single use, plastic coated stir bars for use in stirring Platelet Rich Plasma samples during incubation and testing. Macro Stir Bars are for use with the PAP-4 Series Platelet Aggregation Profilers using Macro Test Tubes.			
IVDR RISK CLASS / COMMON SPECIFICATIONS			
Device Classification		Common Specifications	
Class	A non-sterile	No relevant common specifications have been published yet.	
Rule	5c per Annex VIII of IVDR 2017/746		

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 An ISO 13485 Registered Company



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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 be "W. Trolio", is written above a horizontal line that serves as a signature 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