



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
Profiler Paper	105598	++G0561055985F
Intended Purpose See Instructions For Use		Photo See website www.biodatacorp.com
For use with the PAP-4 series aggregometer.		

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	

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. Trolie

SIGNATURE:



A handwritten signature in black ink, appearing to read 'W. Trolie', 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: 3 February 2023