# Declaration of Conformity

This United Kingdom Declaration of Conformity is issued under the sole responsibility of the manufacturer.

| **MANUFACTURER** | | |
|---|---|---|
| **Name of Company** | **Address** | **SRN** |
| Bio/Data Corporation | 155 Gibraltar Road,<br>Horsham, PA 19044 U.S.A. | US-MF-000026991 |
| **UK RESPONSIBLE PERSON** | | |
| **Name of Company** | **Address** | **Telephone/email** |
| Alpha Laboratories Ltd | 40 Parham Drive, Eastleigh,<br>Hampshire SO50 4NU<br>UNITED KINGDOM | +44 2380 483000<br>quality@alphalabs.co.uk |
| **PRODUCT IDENTIFICATION** | | |
| **Product / Trade Name** | **Product Code / Catalog Number** | **Basic UDI-DI** |
| AGG/PAK™ 5 Combo Kit | 107650 | ++G0561076501 |
| **Intended Purpose**<br>**See Instructions for Use** | | **Photo**<br>**See website www.biodatacorp.com** |
| AGG/PAK™ 5 Combo Kit is a convenience kit containing a combination of routine platelet aggregation reagents used to elicit aggregation and / or agglutination responses in Platelet Rich Plasma (PRP). This Kit includes ADP, Arachidonic Acid, Collagen, Epinephrine, and Ristocetin Reagents. | | |

| **IVDR RISK CLASS / COMMON SPECIFICATIONS** | | |
|---|---|---|
| **Device Classification** | | **Common Specifications** |
| Class | General IVD (Self Certified) | Sections 1-5 (as modified by Part III of Schedule 2A to the UK MDR 2002) |
| Rule | Part IV of the UK MDR 2002, Annex III | |

**Bio/Data Corporation, the Manufacturer, declares that the above-mentioned product meets the provision of the following UK legislation:**

Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

**Conformity Statement:**

Bio/Data Corporation declares that the above-mentioned products meet the provision of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) for In Vitro Diagnostic Medical Devices.

**Notified Body (NB) Identification, conformity assessment procedure performed and identification if the certificate or certificates issued:**

Not applicable. The conformity assessment procedure for General IVD (non-Annex II) 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:** 

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

**PLACE: Bio/Data Corporation, Horsham, PA 19044 USA** **DATE:** 1 March 2025