



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 | |
| Epinephrine | 101311 | ++G05610131133 | |
| Intended Purpose | | Photo | |
| See Instructions For Use | | See website www.biodatacorp.com | |
| Epinephrine (adrenalin) reagent is for routine use in platelet studies for the evaluation of hypersensitivity of platelets in Platelet Rich Plasma and evaluation of platelet responses to a weak agonist. | | | |
| 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', 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