MICROPOINT

Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Micropoint Biotechnologies Co., Ltd., having our registered office at 3-5F, Building 1, Runheng Electronics Factory, Liuxian 2 Road, Xinan Street, Baoan District, 518101 Shenzhen, China

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

1. qLabs® PT-INR Test Strips (QS-1 Pro);
2. qLabs® Coag Panel 2 Test Strips (QS-4 Pro);
3. qLabs® APTT Test Strips (QS-9 Pro);
4. qLabs® PT-INR Liquid Control (QS-1-CL Pro);
5. qLabs® Coag Panel 2 Liquid Control (QS-4-CL Pro);
6. qLabs® APTT Liquid Control (QS-9-CL Pro);
7. qLabs® ElectroMeter (Q-3 Pro);
8. qLabs® ElectroMeter (Q-3 Plus);
9. qLabs® ElectroMeter (Q-1 Pro);
10. qLabs® ElectroMeter Plus (Q-2 Plus);

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

And they are supported by the following Applicable Harmonized Standards:

Standard	Titles
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

	(ISO 15223-1:2016, Corrected version 2016-12-15)
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2016
EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices EN 13612:2002/AC:2002
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)
EN ISO 18113-5:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)
EN 61010-2-101:2017	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2015
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2012
EN 62304:2006	Medical device software - Software life-cycle processes EN 62304:2006/AC:2008
EN 62366:2008	Medical devices - Application of usability engineering to medical devices IEC 62366:2007

Signatory established within the EU who has been empowered to enter into commitments on our behalf:

European Authorized Representative (E.A.R.)
Obelis S.A.

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Date: 2021-08-23

Stamp: