Genrui

Declaration of Conformity

Certificate No.:EU2021099

Manufacturer:
Genrui Biotech Inc.
4-10F, Building 3, Geya Technology Park, Guangming District, 518106, Shenzhen, China.
Tel: +86 755 26835560 Fax: +86 755 26678789

European Representative:
Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Product Name:
See attachment

Model:
See attachment

Classification:
Others device, not in annex II and not for self-testing, not for performance evaluation.

Conformity Assessment Route:
IVDD 98/79/EC Annex III (excludes section 6)
We here with declare under sole responsibility that the above mentioned products meet the provisions of the Council Directive 98/79/EC on in vitro diagnostic medical devices.

Digitally signed by Iighili Tatiana
Date: 2021.10.20 16:08:05 EEST
Reason: MoldSign Signature
Location: Moldova

General Applicable Directive:
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Standards Applied:

EN ISO 13485:2016	EN 13612:2002	EN ISO 14971:2012	EN ISO 18113-1:2011
EN 62304:2006	EN 61326-2-6:2013	EN 61010-2-101:2002	EN 61326-1:2013
EN 62366:2008	EN ISO 15223-1:2016	EN 61010-1:2010	EN ISO 18113-3:2011

CE

Place, Date of Issue: Shenzhen, June. 24th, 2021
Position Held in Company: Management Representative
Signature:

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Attachment I :

Product Name:
Auto Hematology Analyzer

Model:
KT-6200, KT-6300, KT-6400, KT-6390, KT-6360, KT-6600, KT-6610, KT-6500, KT-6510, KT-60, KT-62, KT-40, KT-42

Including reagents as following:
Probe cleanser, Diluent Solution, KT03(KT03A) Lyse Solution, EZ cleanser, KT05/KT05A DiFF lyse, KT05/KT05A DIL diluent, KT05/KT05A LH lyse

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Attachment II :

Product Name:
Semi-auto Chemistry Analyzer
Auto Chemistry Analyzer
Coagulation Analyzer

Model:
WP21A, WP21B, WP21C, WP21D, WP21E
GS480A, GS450A, GS450, GS300 Plus
CA51, CA52, CA54