

Declaration of Conformity to Council

Directive 98/79/EC

Manufacturer:

Xi'an Tianlong Science&Technology Co.,Ltd.

No.389 Zhuhong Road, Xi'an, Shaanxi Province, 710018,

P. R. China

European representative:

Share Info Consultant Service LLC Repräsentanzbüro

Heerdter Lohweg 83, 40549 Düsseldorf

Product:

Rotary Nucleic Acid Extractor

Model(s):

GeneRotex 96 GeneRotex 48 GeneRotex 24

Classification:

Others

Conformity assessment route: Annex III

We, Xi'an Tianlong Science&Technology Co.,Ltd., herewith declare that the above mentioned product(s) meet the transposition into nation law, the provision of council directive 98/79/EC of the European parliament and of the council of 27 October 1998 on in vitro diagnostic medical devices.

All supporting documentation is retained at the premises of the manufacturer.

This declaration of conformity is issued under the sole responsibility of Xi'an Tianlong Science&Technology Co.,Ltd.

Standards applied:

EN ISO 13485:2016 EN ISO 14971:2012 EN 61010-1:2010 EN 61010-2-010:2014

EN 61010-2-101:2017 EN 61326-1:2013 EN 61326-2-6:2013 EN ISO 18113-1:2011

EN ISO 18113-3:2011 EN 62366-1:2015

CE mark:

CE

Start of CE-marking:

2020-03-26

Place, date of issue:

Xi'an, 2020.03.26

Signature:

Wang Yu

Name of authorized signatory: Ms. Wang Yu

Position held in company:

Manger, Technical Regulation