

# Declaration of conformity to council directive 98/79/EC

Manufacturer: Xi'an Tianlong Science and 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: Nucleic Acid Extractor

Model(s): Libex

Classification: Others

Conformity assessment route Annex III

We, Xi'an Tianlong Science and 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 and Technology co.,ltd.

Standards applied:

EN ISO 13485:2016,EN 1041:2008,EN ISO 15223-1:2016 ,EN ISO 14971:2012,EN 62366-1:2015  
EN 13612:2002,EN ISO 18113-1:2011,EN ISO 18113-3:2011,EN 61010-1:2010,  
EN 61010-2-081:2015,EN 61010-2-101:2015,EN 61326-2-6:2013,EN 61326-1:2013

CE mark:



Start of CE-marking: 2019-07-01

Place, date of issue: Xi'an,2019.07.02

Signature:

A handwritten signature in black ink, appearing to be 'Wang Yu'.

Name of authorized signatory: Ms.WangYu

Position held in company: Manger, Technical Regulation