Declaration of Conformity

Manufacturer:
Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District, 518122 Shenzhen, P.R. China
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European Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: +49-40-2513175 Fax: +49-40-255726

Product Name:
Product identifications see the attachment

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

Conformity Assessment Route: Annex Ⅲ (IVDD 98/79/EC)
We herewith declare under sole responsibility that the following mentioned products meet the provisions of the Council Directive 98/79/EC on *in vitro* diagnostic medical devices. All supporting documentations are retained at the premises of the manufacturer.

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 ISO 15223-1:2016 EN ISO 18113-1:2011 EN ISO 14971:2012
EN ISO 18113-3:2011

First Start of CE-MARK: Feb. 1, 2021

Signature: General Director

Place, Date of Issue: Shenzhen, Feb. 23, 2021

Attachment

Item	Product Name	Cat. No.
1	Reaction Module	630003
2	Waste Bag	21060726
		21060625
		21060624
		130210000201
		130210000101
3	Cuvette	010102000901
4	Reaction Cup	130105000101
5	Tip	130207000501
6	8-Strip Tip	132131002H
7	96-Well Deep-Well Plate	132131003H
8	Ion Selective Electrode	073101003201 073101002601 073101002401 073101002701 073101002801 073101000401

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