Declaration of Conformity

Manufacturer:
Shenzhen New Industries Biomedical Engineering Co., Ltd.
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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 18113-2:2011

First Start of CE-MARK: April 16, 2009

Signature: Managing Director 

Place, Date of Issue: Shenzhen, Dec. 09, 2019

Attachment

Item	Product Name	Cat. No.
1	Starter 1+2	130299004M 130299012M
2	Wash Concentrate	130299005M
3	Light Check	130299006M
4	System Tubing Cleaning Solution	130299007M
5	Alkaline Wash	1305990001
6	Acid Wash	1305990002
7	Hitergent	1305990003
8	ISE Cleaner	1305990004