



杭州隆基生物技术有限公司
Hangzhou Clongene Biotech Co., Ltd.

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EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang Sub-district
Yuhang District
311121 Hangzhou
China

We declare under our sole responsibility that

the medical device: Fecal Occult Blood Rapid Test Cassette
Fecal Occult Blood Rapid Test Strip

of class: Other
according to article 9 of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure: Directive 98/79/EC Annex III, excluding Section 6

Applicable standards:	EN ISO 13485:2016	EN ISO 15223-1:2021
	EN ISO 18113-1:2011	EN ISO 18113-2:2011
	EN ISO 23640:2015	EN ISO 14971:2019
	EN 13641:2002	EN13612:2002/AC:2002
	EN 13975:2003	EN 62366-1:2015
	EN ISO 17511:2021	

Name and address of the authorized representative: Shanghai International Holding Corporation GmbH (Europe)
Eiffestrasse 80
20537 Hamburg
Germany

Hangzhou, April 14, 2022

Place, date

杭州隆基生物技术有限公司
HANGZHOU CLONGENE BIOTECH CO., LTD.

Shujian Zheng, Legal representative
Name and function