



DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III.

Manufacturer: Biochain (Beijing) Science Technology, Inc.

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In Vitro Diagnostic Directive:

Septin9 Gene Methylation Detection Kit for Human Colorectal Cancer (Real-Time PCR)

Category: Others.

Conformity assessment route: Declaration of Conformity IVDD Annex III

Applicable Standards:

ISO 13485:2016

EN ISO 18113-3:2011

EN 13612:2002

ISO 14971:2019

EN 13641:2002

ISO 23640:2015

EN ISO 18113-1:2011

ISO 15223-1:2016

EN 62366-1:2015

EN ISO 18113-2:2011

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on

Name of authorized signatory: 

Position held in the company: Chairman

Seal/Stamp:

Biochain (Beijing) Science Technology, Inc.

Place: Beijing, China

