CE

Declaration of Conformity

Manufacturer: BGI Europe A/S

Address: Ole Maaløes Vej 3, DK-2200 Copenhagen N, Denmark

Device: Real-time fluorescent RT-PCR kit for detecting 2019-nCoV

Catalogue number: MFG030010

Classification (IVDD, Annex II): Others

Conformity assessment route: ANNEX III

We herewith declare that the above mentioned product meets the provisions of the following EC Council Directives and Standards (IVDD 98/79/EC). All supporting documentations are retained under the premises of the manufacturer.

General applicable directives:

IVDD 98/79/EC: Council Directive 98/79/EC concerning in vitro diagnostic medical devices

Standard & Guideline:

No.	Standards No.	Standards Title
1.	MEDDEV 2.12.1: 2013 (Rev.8)	Guidelines on a medical device vigilance
2.	MEDDEV. 2.14/3 rev.1	IVD GUIDANCES: Supply of Instructions For Use (IFU) and other information for In-vitro Diagnostic (IVD) Medical Devices
3.	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
4.	BS EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
5.	EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
6.	EN ISO 18113-1:2011	vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
7.	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use IVD
8.	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9.	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
10.	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents

Date CE mark was first affixed: 2020-02-24

华大基因 BGI

Signed by: General Manager Date: 2020.02.25