NGeneBio

NGB-RA-004-01E(2)

EC Declaration of Conformity

Manufacturer:

Name： NGeneBio Co., Ltd.

Address： Daerung Post-tower 1 Bldg, 288, Digital-ro, Guro-gu, Seoul, 08390, Korea

European Representative:

Name: CMC MEDICAL DEVICES & DRUGS, S.L.

Address: C/ Horacio Lengo No 18, CP 29006, Málaga-Spain

Product Name	Model	Classification	Conformity assessment route
BRCAaccuTest	IVD reagents	Non listed devices of IVDD 98/79/EC	IVDD 98/79/EC Annex III
NGeneAnalySys	IVD Software	Non listed devices of IVDD 98/79/EC	IVDD 98/79/EC Annex III

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Standard Applied:

BS EN ISO9001:2015, BS EN ISO13485:2016, BS EN ISO14971:2012, BS EN ISO 18113-1:2011, BS EN ISO 18113-2:2011, BS EN ISO 23640:2015, BS EN ISO 15223-1:2016, BS EN 13612:2002, BS EN ISO 17511:2003

Registration Number: RPS / 457 / 2017

Place: Seoul, Korea

Date of Issue: 20, Jan, 2020

Signature: CEO, Daechul Choi