generi biotech

EC DECLARATION OF CONFORMITY

in compliance with

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices including amendments

Manufacturer: **GENERI BIOTECH s.r.o.**
Machkova 587/42, 500 11 Hradec Kralove 11 – Trebes, Czech Republic

hereby declares, that **real-time PCR kits** as *In vitro diagnostic medical devices (IVD)* listed below:

gb Human B2M mRNA	Cat. no. 3153-100 and 3153-500
gb Sarbeco E (primary test)	Cat. no. 3227-100 and 3227-500
gb SARS-CoV-2 RdRP (confirmation test)	Cat. no. 3228-100 and 3228-500
gb Sarbeco N (primary test)	Cat. no. 3229-100 and 3229-500
gb SARS-CoV-2 N (confirmation test)	Cat. no. 3230-100 and 3230-500
gb SARS-CoV-2 Multiplex	Cat. no. 3231-50, 3231-200, and 3231-500
gb SARS-CoV-2 Combi	Cat. no. 3232-100 and 3232-500
gb SARS-CoV-2 Influenza A/B	Cat. no. 3233-100 and 3233-500
gb SARS-CoV-2 Multiplex EndoC	Cat. no. 3234-100, 3234-500 and 3234-M
gb SARS-CoV-2 Combi EndoC	Cat. no. 3235-100, 3235-500 and 3235-M
gb ONCO BRAF (V600E)	Cat. no. 3241-024 and 3241-048
gb ONCO EGFR (T790M)	Cat. no. 3245-024 and 3245-048
gb ONCO BCR-ABL DETECT	Cat. no. 3246-048
gb ONCO BCR-ABL MAJOR / GUSB	Cat. no. 3249-048 and 3249-096
gb GENETIC HLA-B*27	Cat. no. 3257-025 and 3257-100
gb ONCO BRAF (V600)	Cat. no. 3281-024 and 3281-048

comply with the essential requirements of ***Annex I of the Directive 98/79 EC*** including amendments. The conformity was established according to ***Annex III*** (class: other IVD products) ***of the Directive 98/79 EC***.

Following harmonized technical standards were used to demonstrate the compliance:

EN ISO 13485:2016
EN ISO 18113-2:2011
EN ISO 23640:2015
EN 13612:2002
EN ISO 14971:2019
EN ISO 15223-1:2016

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In: Hradec Kralove
Date: 9. 11. 2020

PharmDr. Radovan Haluza, Ph.D.
CEO and Managing Director