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 PHARM DPYD*2A	Cat. no. 3210-025
gb HEMO EPCR (G4678C)	Cat. no. 3214 and 3214-025
gb GENETIC Gilbert	Cat. no. 3216-050 and 3216-025
gb PHARM TPMT	Cat. no. 3217-050 and 3217-025
gb GENETIC LACTO	Cat. no. 3219-050 and 3219-025
gb MICRO Aspergillus fumigatus	Cat. no. 3225-050 and 3225-025
gb PHARM Warfarin	Cat. no. 3250-050 and 3250-025
gb GENETIC A1AT	Cat. no. 3251-050 and 3251-025
gb GENETIC FRUCTO	Cat. no. 3252-050 and 3252-025

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 14971:2012
EN ISO 15223-1:2016

In: Hradec Kralove
Date: 21. 4. 2020

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