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 **RNA extraction kit** as *In vitro diagnostic medical device (IVD)* listed below:

viRNAtrap™ Extraction Kit Cat. no. 3315-M, 3315-500, and 3315-100

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

In: Hradec Kralove
Date: 27. 10. 2020

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