



Certificate of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

GeneAll Biotechnology Co.,Ltd.
GeneAll Bldg., 303-7,
Dongnam-ro, Songpa-gu
Seoul, 138-859
Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).
The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.
This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

14 May 2021

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I

**GeneAll Biotechnology Co.,Ltd.**

Annex I

to "Certificate of EU Product Notification"

(List of CE marked Products)

Page 1 / 1 of Annex I

Internal Reference Number	Product Name (Model name)	Registration Number (at the German CA/DIMDI) DE/CA70/40838/	Product Category (EDMS)	EDMS Code Description	Classification Annex
GAB-01	Ribospin™ vRD (302-150)	DE/CA70/40838-163426	14 02 06 01 00	Nucleic Acid Identification - manual	III
GAB-01	Ribospin™ vRD (302-103)	DE/CA70/40838-163426	14 02 06 01 00	Nucleic Acid Identification - manual	III
GAB-01-01	GENTi™ Viral DNA/RNA Extraction Kit (902-096; 902-048)	DE/CA70/40838-163426	14 02 06 01 00	Nucleic Acid Identification - manual	III
GAB-01-02	GENTi™ Advanced Viral DNA/RNA Extraction Kit (902-096A; 902-048A)	DE/CA70/40838-163426	14 02 06 01 00	Nucleic Acid Identification - manual	III
GAB-01-03	Exgene™ Clinic SV (108-152, 108-101, 108-201, 108-226, 108-310, 108-326)	DE/CA70/40838-163426	14 02 06 01 00	Nucleic Acid Identification - manual	III
GAB-01-04	Hybrid-R™ Blood RNA (315-150)	DE/CA70/40838-163426	14 02 06 01 00	Nucleic Acid Identification - manual	III
GAB-01-05	GENTi™ Advanced Genomic DNA Extraction Kit (901-096A, 901-048A)	DE/CA70/40838-163426	14 02 06 01 00	Nucleic Acid Identification - manual	III



GAB-02	GENTi™ Advanced Automatic Extraction Equipment (GTI032A)	DE/CA70/40838- 159379	26 02 09	Multiple Purpose Sample Processors	III
GAB-02-01	GENTi™ Automatic Extraction Equipment (GTI032)	DE/CA70/40838- 159379	26 02 09	Multiple Purpose Sample Processors	III

14 May 2021

Dr. Michael Rinck
- Managing Director -

