Declaration of Conformity

Manufacturer	Abbott Diagnostics Korea Inc. 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099, Republic of Korea
European Representative	MT Promedt Consulting GmbH Altenhofstrasse 80 66386 St. Ingbert Germany
Product Designation	Bioline™ Rota/Adeno
EDMS Code	15 04 80 06 00 [Rotavirus] / 15 04 80 01 00 [Adenovirus]
Catalogue No.	14FK20
Classification	Others ; Self-Declaration IVD - No self-test - No annex II List A or List B

Conformity Assessment Route Annex III Applied (IVDD 98/79/EC)

We herewith declare that above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

Standard Applied	List of (Harmonized) standards for which documented evidence for compliance can be provided.
	* EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016 Certificate No. : Q5 043136 0055 Rev. 00
Start of CE marking	Feb. 06, 2015
Date of Issue	Apr. 20, 2022
Place of Issue	Yongin

On the behalf of
Abbott Diagnostics Korea Inc.

Signature

Jung, Jae-Ho
Site Director