DNAgenotek™

Product change notification

Products affected:

Device brand name	Model/Catalog number/REF
ORAcollect™•DNA	OCR-100, OCR-100.XXX
ORAcollect™•RNA	ORE-100, ORE-100.XXX
ORAgene™•Dx	OGD-500, OGD-500.XXX, OGD-510, OGD-510.XXX OGD-600, OGD-600.XXX, OGD-610, OGD-610.XXX OGD-575, OGD-575.XXX, OGD-675, OGD-675.XXX
ORAgene™•ONE	ON-500, ON-500.XXX, ON-600, ON-600.XXX
OMNIgene™•ORAL	OME-505, OME-505.XXX
OMNIgene™•GUT Dx	OM-200, OM-200.XXX
prepIT™•L2P	PT-L2P-5, PT-L2P-45
OMNIgene™ Liquefaction reagent	OM-LQR-400, OM-LQR-1600

Effective date of change: By December 31, 2024

Change description:

DNA Genotek Inc. is updating the product labeling and Instructions for Use (IFU) for the affected products to include the new Authorized Representative (AR) information for Europe, Switzerland and the United Kingdom. The labeling change for these affected products will be implemented over the remainder of 2024, to be concluded no later than December 31, 2024.

There has been no change to the products' performance as a result of this labeling update. Device labeling will change from the current Authorized Representative to the new Authorized Representative, as follows:

Jurisdiction	Current authorized representative	New authorized representative
Europe and Northern Ireland	EC REP Novosanis NV, Bijkhoevelaan 32c, 2110 Wijnegem, Belgium	EC REP Qarad EC-REP BV, Pas 257, 2440 Geel, Belgium
United Kingdom	UK REP Emergo Consulting (UK) Limited c/o Cr360 – UL International, Compass House, Vision Park Histon, Cambridge, CB24 9BZ	UK REP Qarad UK Ltd., 8 Northumberland Ave, Westminster, London, WC2N 5BY United Kingdom
Switzerland	CH REP Arazy Group Swiss GmbH Bruderholzallee 53, 4059 Basel, Schweiz	CH REP Qarad Suisse S.A., World Trade Center, Avenue Gratta-Paille 2, 1018 Lausanne, Switzerland

Reason for change:

We are making this transition to streamline our regulatory processes and better support our customers.

DNA Genotek actions:

We are in the process of updating product labeling to reflect this change. Products currently in inventory, in distribution or transit, in use with the end-user or already shipped from DNA Genotek will still bear the current Authorized Representative information. These products remain in compliance with CE-marking requirements and other applicable regulatory requirements, as they were duly CE marked, registered and placed on the market prior to this change.

Customer action:

- No actions are required for DNA Genotek products already in your inventory, in distribution or in use, as this is an administrative change with no impact to product intended use, safety, performance or regulatory compliance.
- Update your internal documentation and/or processes, as required.

If you have any questions or want to discuss this product change notification, contact your account manager or email info@dnagenotek.com.