

Product change notification

This change notification pertains to the name and address of the UK Responsible Person (UKRP), which is required on the product label for products registered and distributed in the United Kingdom.

Change description:

Our UKRP, Qarad UK Ltd., has undergone an update to their company name and registered address. The change comes as part of the integration of Qarad UK Ltd. into the QbD Group. The legal entity remains the same and all rights and obligations to which Qarad UK Ltd. was subject will continue to apply to QbD RepS UK Ltd. All impacted DNA Genotek™ products remain in compliance with UKCA requirements and other applicable regulatory requirements.











Previous name and registered address	New name and registered address
Qarad UK Ltd. 8 Northumberland Ave Westminster, London WC2N 5BY United Kingdom	QbD RepS UK Ltd. Waterside, Unit 33 Schooner Court 44–48 Wharf Road London, N1 7UX United Kingdom

DNA Genotek is updating product labels to reflect the new UKRP name and registered address change. While the transition is underway and until inventory is depleted, you may receive devices with the previous UKRP name and address on the product labeling. Throughout the transition, products in your inventory, in distribution or transit, in use with the end user, or labeled with the previous name and registered address can continue to be used without limitation.

Customer impact:

- There is no impact on product use or compliance. Products with either the previous UKRP name and registered address on the product labeling can be used without limitation. This inclusion applies to product in your inventory, in distribution or in use. This change is administrative and does not impact product intended use, safety, performance or regulatory compliance.
- For purchasers of customized devices with the UKRP registered address on the device packaging (i.e., custom branded mailing box, custom instructions for use), your account manager will contact you to discuss artwork changes.

Products affected:

Product brand name	Model/Catalog number/REF
 ORACollect™·DNA	OCR-100
 ORACollect™·RNA	ORE-100
 ORAgene™·Dx	OGD-500, OGD-510, OGD-575, OGD-600, OGD-610, OGD-675
 ORAgene™·ONE	ON-500, ON-600
 OMNigene™·ORAL	OME-505
 OMNigene™·GUT	OM-200, MP-017
prepIT™·L2P	PT-L2P-5, PT-L2P-45
 OMNigene™ Liquefaction reagent	OM-LQR-400
 Colli-Pee™	Colli-Pee FV-5004 N00290 Colli-Pee FV-5010 N00309 Colli-Pee FV-5020 N00055 Colli-Pee FV-5040 N00269
 Colli-Pee™ UCM™	Colli-Pee UCM FV-5004 N00260 Colli-Pee UCM FV-5010 N00327 Colli-Pee UCM FV-5010 N00327_P Colli-Pee UCM FV-5020 N00176
 Colli-Pee™ UAS™	Colli-Pee UAS FV-5040 N00342

All related customizations containing the UKRP name or registered address are considered in scope and will be updated accordingly.

For issues or concerns related to this product change notification, email info@dnagenotek.com.