

Product change notification

This change notification pertains to the name and address of the European Union Authorized Representative (EU AR), which is required on the product label for products registered and distributed in the EU.

Change description:

In Q4 2024, our EU AR, Qarad EC-REP BV, has undergone a change of name and address. The change comes as part of the integration of **Qarad EC-REP BV** into the **QbD Group**.

The legal entity remains the same and all rights and obligations to which Qarad EC-REP BV was subject will continue to apply to QbD RepS BV. Their VAT number, banking details and Single Registration Number in EUDAMED (BE-AR-000000040) remain unchanged.

All impacted DNA Genotek products remain in compliance with CE-marking requirements and other applicable regulatory requirements.

Previous name and address:	New name and address:
Qarad EC-REP BV Pas 257 2440 Geel Belgium	QbD RepS BV Groenenborgerlaan 16 2610 Wilrijk Belgium



DNA Genotek is updating product labels to reflect the new EU AR name and address change. While the transition is underway and inventory is depleted, you may receive devices with the previous EU AR name and address on the product labeling, or a combination of the previous and new EU AR name and address.









Throughout the transition, products in your inventory, in distribution or transit, in use with the end user, or labeled with the previous name and address can continue to be used without limitation.

Customer impact:

- No impact. Products with either the previous EU AR name and address on the product labeling, or a combination of the previous and new EU AR name and address, 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 a customized device that contains the EU AR 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, 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	OM-200, OM-200.XXX, MP-017
prepiT™ L2P	PT-L2P-5, PT-L2P-45
 OMNigene™ Liquefaction reagent	OM-LQR-400
 ORAgene™	OG-AC1
 Colli-Pee™	Colli-Pee FV-5004 N00290 Colli-Pee FV-5010 N00309 Colli-Pee FV-5020 N00055 Colli-Pee FV-5020c N00238 Colli-Pee FV-5040 N00269
 Colli-Pee™ UCM™	Colli-Pee UCM FV-5004 N00260 Colli-Pee UCM FV-5010 N00327 Colli-Pee UCM FV-5020 N00176 Colli-Pee UCM FV-5003b N00383
 Colli-Pee™ UAS™	Colli-Pee UAS FV-5040 N00342

For issues or concerns pertaining to this product change notification, contact info@dnagenotek.com.

