DNAgenotek™

Product change notification

Products affected: ORAgene™·Dx ORAgene™·DNA ORAcollect™·Dx ORAcollect™·DNA ORAcollect™·RNA

Catalog number/SKU: OGD-575, OGD-675, OG-575, OG-675, OCD-100, OCD-100A, OCR-100, ORE-100

Effective date of change: July 1, 2023

Change description:

In accordance with European Union (EU) Medical Device Regulation (MDR 2017/745) and In Vitro Diagnostic Regulation (IVDR 2017/746), DNA Genotek has appointed Novosanis NV as EU Authorized Representative, effective July 1, 2023.

Device labeling will change from Emergo Europe to Novosanis NV, as follows:

Emergo Europe address	Novosanis NV
EC REP Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, Netherlands	EC REP Novosanis NV, Bijkhoevelaan 32c, 2110 Wijnegem, Belgium Email: EUAR@novosanis.com

Reason for change:

We are making this transition to streamline our regulatory processes and better support our customers with CE-marked products.

DNA Genotek actions:

We are in the process of updating product labeling to reflect this change. Please note that products currently in inventory, in distribution or transit, in use with the end-user, or already shipped from DNA Genotek will still bear "Emergo Europe" as EU Authorized Representative. These products remain in compliance with CE-marking requirements, as they were duly CE marked 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 CE-marking compliance.
- Update your internal documentation and/or processes, as required.
- Should you need to contact the DNA Genotek EU Authorized Representative, i.e., for incident reporting, please e-mail **EUAR@novosanis.com** beginning July 1, 2023.

Contact **info@dnagenotek.com** if you have any issues or concerns pertaining to this product change notification.