

## Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

| <b>MANUFACTURER</b>    |  |                 |
|------------------------|--|-----------------|
| <b>Name of Company</b> | <b>Address</b>   | <b>SRN</b>      |
| DNA Genotek Inc.       | 3000 - 500 Palladium Drive,<br>Ottawa, Ontario K2V 1C2, Canada | CA-MF-000003486 |

| <b>AUTHORIZED REPRESENTATIVE</b> |  |                 |   |
|----------------------------------|--|-----------------|---|
| <b>Name of Company</b>           | <b>Address</b>   | <b>SRN</b>      | <b>Telephone/email</b>                      |
| Emergo Europe                    | Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | NL-AR-000000116 | Tel: +31.70.345.8570<br>EmergoEurope@ul.com |

| <b>PRODUCT IDENTIFICATION</b>  |                                      |                     |
|--|--------------------------------------|---------------------|
| <b>Product Name</b>  | <b>Product Code / Catalog Number</b> | <b>Basic UDI-DI</b> |
| ORAcollect®·DNA  | OCR-100, OCR-100.XXX                 | 0627595B0200EX      |
| <b>Intended Use/Intended Purpose</b>   |                                      |                     |
| ORAcollect®·DNA is designed for the collection and stabilization of DNA from human oral samples. |                                      |                     |

| <b>RISK CLASS FOR MEDICAL DEVICES</b> |  |                          |
|---------------------------------------|--|--------------------------|
| <b>Device Classification</b>          | <b>Common Specifications</b>                 | <b>Standards Applied</b> |
| Class I, Rule 5<br>(Self-Certified)   | N/A, no common specifications are applicable | BS EN ISO 13485:2016     |

DNA Genotek Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

- **Medical Devices Regulation (EU) 2017/745**

**COMPANY REPRESENTATIVE:** Austin Udacor

**TITLE:** Senior Regulatory Affairs Manager

**PLACE:** Ottawa, Ontario, Canada



**SIGNATURE:**

**DATE:** 28 April 2021 [2021-04-28]