

Declaration of Conformity

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

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

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

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

RISK CLASS FOR MEDICAL DEVICES		
Device Classification	Common Specifications	Standards Applied
Class I, Rule 5 (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]