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®·RNA	ORE-100, ORE-XXX	0627595C0300FF
Intended Purpose		
For the collection and stabilization of RNA from human saliva samples.		

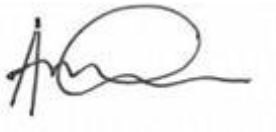
RISK CLASS FOR MEDICAL DEVICES		
Device Classification	**Common Specifications**	**Standards Applied**
Class I, Rule 5 (Self-Certified)	N/A, no common specifications are applicable	BS EN ISO 13485:2016

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 Udocor

TITLE: Senior Regulatory Affairs Manager

SIGNATURE: 

PLACE: Ottawa, Ontario, Canada

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