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**
Oragene®·DNA	OG-575, OG-675, OG-575.XXX, OG-675.XXX	0627595A0100EF
Oragene®·Dx	OGD-575, OGD-675, OGD-575.XXX, OGD-675.XXX	0627595A0100EF
Intended Purpose		
The devices are intended for the collection, stabilization, storage and transportation of human nucleic acids (DNA) from saliva or oral samples.		

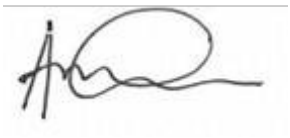
RISK CLASS FOR MEDICAL DEVICES		
Device Classification	**Common Specifications**	**Standards Applied**
Class I, Rule 5 (Self-Certified)	N/A, no common specifications are applicable	BS EN ISO 13485:2016

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 Udocor

TITLE: Senior Regulatory Affairs Manager

SIGNATURE: 

PLACE: Ottawa, Ontario, Canada

DATE: 30 April 2021 [2021-04-30]