EU Declaration of Conformity

DnaNudge Ltd declares that the products listed below are in compliance with the provisions of the Council Directive 98/79/EC for in vitro diagnostic devices and the requirements set out within the listed directives. The Declaration of Conformity is issued under the sole responsibility of DnaNudge Ltd (the manufacturer).

Manufacturer:	DnaNudge Limited Level 11, The Translation and Innovation Hub, Imperial College White City Campus, London W12 0BZ, UK
Product Number:	BX-0004
Product Description	NudgeBox Analyser

*Please refer to Annex 1. Product List on page 2 for additional details

Conformity Assessment Procedure:	Annex III (IVDD 98/79/EC)
Product Classification:	General IVD (Not identified under List A or B)
GMDN Code:	62875; Thermal cycler nucleic acid amplification analyser IVD, point-of-care

Is in conformity with the requirements of the following EC directives:

98/79/EC	In Vitro Diagnostic Medical Devices
2014/53/EU	Radio Equipment Directive (RED)
2014/30/EU	EMC Directive
2011/65/EU	RoHS 2 Directive
2012/19/EU	WEEE Directive

The following standards have been applied:

EN 62304	Medical Device Software – Software Lifecycle processes
IEC61010:2010-1/AMD1:2016/COR1:201	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN 61010-1;	Safety requirements for electrical equipment for measurement, control, and laboratory use; General Requirements
IEC 61010-2-010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-101	Safety requirements for electrical equipment for measurement, control, and laboratory use: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-1:2010+A1:2019	Safety requirements for electrical equipment for measurement, control, and laboratory use - General requirements
EN 60601-2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 61326-2-6	Electrical equipment for measurement, control and laboratory use - EMC requirements: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971,	Medical devices - Application of risk management to medical devices
UNE-EN ISO 18113-3:	In vitro diagnostic medical devices information provided by the manufacturer.

EU Authorised Representative:	Alfredo García de Tuñón Calle Cervantes, 6 33004 Oviedo Spain

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Authorised Signatory: Name: Andrew Rogers
Title: Head of Quality Assurance & Regulatory Affairs

Signature: 

Annex 1. Product List:

Item Description		Product Code
NudgeBox Analyser		BX-0004
	NudgeBox Kit	9101004
	Health Check Cartridge	9101003
	Capsule (DnaBean)	9101005
CovidNudge DnaCartridge		CT-0001

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