CLINICALDESIGN

EU DECLARATION OF CONFORMITY

PRODUCT
Urine Testing System™

NAME AND ADDRESS OF THE MANUFACTURER
Clinical Design Technologies Ltd., Teign Road, Newton Abbot, Devon. TQ12 4AA. UK

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer

OBJECT OF THE DECLARATION
Clinical Design Technologies Ltd hereby declare that the Urine Testing System™ and its constituent products described below are In vitro Diagnostic Medical Devices (IVDD) in accordance with Article 1 paragraphs 2a), 2b) and 2c) of Directive 98/79/EC:

UTS DA	Urine Testing System Digital Analyser™
UTS-10 Cap	Urine Testing System UTS-10 Cap™
UTS Tube and lid	Urine Testing System Tube and lid

The object of the declaration described above is in conformity with the relevant EU harmonisation legislation:
Complies with the Essential Requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998
on in vitro diagnostic Medical Devices.

Additionally, the products described above comply with the essential and applicable elements of the following Harmonised Standards (HAS)
and Non-Harmonised Standards:

EN ISO 13485:2016	BS EN ISO 6717:2021	EN ISO 14971:2019	EN 13612:2002
EN 62366:2015	EN ISO 18113-1:2011	EN ISO 18113-3:2011	EN ISO 15223-1:2021
EN ISO 23640:2015	EN 61010-1:2010	EN 61326-2-6:2020	EN 62304:2006
IEC EN 61010-2-101:2018			

See attached Appendix I and II for more detail.

Signed for and on behalf of Clinical Design Technologies Ltd.

Full name and position of signatory. Date: 24th March 2022

Oliver Blackwell (CEO)

Expiry date: 24th March 2024

Declaration of Conformity Addendum

UTS – Urine Testing System™

History of amendments:

Amended in	Amendment	Details	Date
Addendum Version 1	Expiry date, 24th March 2024 at the bottom of Declaration – Not Applicable	This declaration continues to confirm the manufacturers compliance to the IVD Directive 98/79/EC and to IVDR 2017/746 Article110 provisions while transitioning devices to the IVDR. Declaration validity subject to applicable IVDR transitional deadlines.	30th April 2024

Name: Oliver Blackwell

Position: CEO

Signed:

Date:

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.