Abbott Toxicology Ltd.

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of Abbott Toxicology Ltd, and states that the in vitro diagnostic (IVD) medical device identified below meets the essential requirements of the IVD Directive 98/79/EC Annex I.

Name:	**Reference Number:**
SoToxa™ Oral Fluid Mobile Test System	TOX400SUK
SoToxa™ Oral Fluid Mobile Test System	TOX400SUS
SoToxa™ Oral Fluid Mobile Test System	TOX400SAUS
SoToxa™ Oral Fluid Mobile Test System	TOX400SEU
SoToxa™ Oral Fluid Mobile Test System	TOX400SHO
SoToxa™ Oral Fluid Mobile Test System	TOX400SUKR
SoToxa™ Oral Fluid Mobile Test System	TOX400SUSR
SoToxa™ Oral Fluid Mobile Test System	TOX400SAUSR
SoToxa™ Oral Fluid Mobile Test System	TOX400SEUR
SoToxa™ Oral Fluid Mobile Test System	TOX400SHOR
SoToxa™ Oral Fluid Mobile Analyser	TOX400P
SoToxa™ Oral Fluid Mobile Analyser	TOX400PR
SoToxa™ Oral Fluid Mobile Analyser	TOX400016
SoToxa™ Oral Fluid Mobile Analyser	TOX400017
SoToxa™ Oral Fluid Mobile Analyser	TOX400PHO
SoToxa™ Oral Fluid Mobile Analyser	TOX400PRHO
SoToxa™ Oral Fluid Mobile Analyser	TOX400017HO
SoToxa™ Oral Fluid Test Kit	TOX403
SoToxa™ Oral Fluid Test Kit	TOX404
SoToxa™ Oral Fluid Test Kit	TOX408

Classification: General IVD

Conformity assessment procedure: 98/79/EC, Annex III

List of applicable standards:

Standard Reference	Title
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 23640:2015	*In vitro* diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents
EN 62304:2006	Medical device software – Software life-cycle processes
EN ISO 18113-1:2011	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements

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Standard Reference	Title
EN ISO 18113-2:2011	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling) Part 2: *In vitro* diagnostic reagents for professional use
EN ISO 18113-3:2011	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labelling) Part 2: *In vitro* diagnostic instruments for professional use
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied
EN 61010-1:2010	Safety requirement for electrical equipment for measurement, control and laboratory use – Part 1: General Requirements
EN 61010-2-101:2002	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements.
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use. EMC requirements. Part 2-6: Particular requirements - *in vitro* diagnostic (IVD) medical equipment.
EN 61000-6-1:2007	Electromagnetic compatibility (EMC). Generic standards. Immunity for residential, commercial and light-industrial environments.
EN 61000-6-3:2007	Electromagnetic compatibility (EMC). Generic standards. Emission standard for residential, commercial and light-industrial environments.

Legal Manufacturer: Abbott Toxicology Ltd
Legal Manufacturer's Address: 21 Blacklands Way, Abingdon, Oxfordshire, OX14 1DY, United Kingdom

EC Representative's Name: Medical Device Safety Service GmbH (MDSS GmbH)
EC Representative's Address: Schiffgraben 41, 30175 Hannover, Germany

Abbott Toxicology Ltd declares that this device is in conformity with the IVD Directive 98/79/EC.

Abbott Toxicology Ltd declares that all configurations of the SoToxa™ Oral Fluid Mobile Analyser and SoToxa™ Oral Fluid Mobile Test System as outlined in page one of this document are in compliance with the following pieces of legislation:

- EMC Directive 2004/108/EC
- Low Voltage Directive 2006/95/EC
- RoHS Directive 2011/65/EU, including amendment (EU)2015/863

Issued by: Signature:.....
Name: Martyn Rogers
Function: Director of Quality and Regulatory Affairs

Place and date of issue: Abingdon, Oxfordshire, UK, 01st September 2021