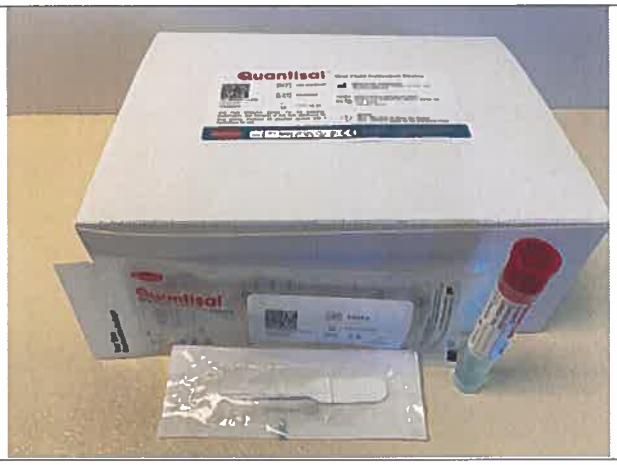
Abbott	**Technical Documentation for Quantisal™ Oral Fluid Collection Device (QSI-0025NINT, QSI-0500NINT)** **(Section 0.9 Declaration of Conformity)**

This declaration of conformity is issued under the sole responsibility of Immunalysis Corporation.

Item	Details
Manufacturer	IMMUNALYSIS CORPORATION 829 Towne Center Drive Pomona, CA 91767 Phone: (909) 482-0840 PRRC: Nancy Bengtson Telephone Number: 1 (224) 668 9578 Email: nancy.bengtson1@abbott.com
Manufacturer Single Registration Number (SRN)	US-MF-000001555
Authorized Representative	Abbott Rapid Dx Internal Limited (RDIL) Parkmore East Business Park Ballybrit, Galway, Ireland H91 VK7E PRRC: Simon Richards Telephone number: +44 (0) 7785 38705 Email: simon.richards@abbott.com
Authorized Representative Single Registration Number	IE-AR-000000091
Device	Quantisal™ Oral Fluid Collection Device
Catalog Number(s)	QSI-0025NINT, QSI-0500NINT
Basic UDI-DI	00840937QUA0001AD
Device Classification	Class I per EU Medical Device Regulation 2017/745 Annex VIII, Rule 5, non-sterile, non-measuring invasive device
Intended Purpose	The Quantisal™ Oral Fluid Collection Device is intended for the collection, preservation, and transport of oral fluid specimens for analytical testing of drugs or drug metabolites. This device is for use only under observed collections.
Image of the Device[1]	
Other Applicable Union Legislations	REACH EC 1907/2006 CLP 1272/ 2008
Applicable Common Specifications (CS)	Not applicable
Notified Body	Not applicable

[1] Images are not to scale. They are provided for visual reference only.

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Item	Details
Conformity Assessment Procedure	Annex II and Annex III
QMS Certificate#	The ISO 13485:2016 standard is applied to all the devices manufactured at the Immunalysis manufacturing facility, including the subject devices Certificate Number: MD 723143 ***Immunalysis ISO 13485:2016 Certificate (D10016325)***
CE Certificate#	Not applicable: self-certification of Class I non-measuring, non-sterile device
Document Version#	D10029933 vAA

On behalf of Immunalysis Corporation listed above, I hereby confirm that the device(s) identified above conform(s) with:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and
- Any other applicable requirements of union legislations as identified above.

Declared By:

Item	Detail	Item	Detail
Name:	Nancy Bengtson	**Signature:**	
Job Title:	Director Regulatory Affairs	**Date of issue:**	6 MAY 2022
Place of issue	Immunalysis Corporation, a subsidiary of Abbott Laboratories		