
**Declaration of Conformity
For
LABType™ SSO DNA Typing Tests**

Manufacturer: One Lambda, Inc.
22801 Roscoe Boulevard
West Hills, CA 91304
U.S.A.

Product: LABType™ SSO DNA Typing Tests - See Declaration of Conformity
List (attached)

Classification: IVDD, General IVD, not listed in Annex II and not intended for
self-testing

Conformity assessment
Route: Annex III (EC Declaration of Conformity) - Self Declaration

We, the manufacturer, declare that the above mentioned products comply with the In Vitro
Diagnostic Medical Devices Directive 98/79/EC.

Authorized Representative: Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

LABType™ SSO DNA Typing Tests were designed and manufactured in accordance with the
following standards: EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2021,
EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN 13975:2003,
EN 14136:2004, EN ISO14971:2019, EN ISO 15225:2016, EN 62366-1:2015



Angela Estany
Sr. Director, Regulatory Affairs & Quality Systems

Electronically signed
by: Angela Estany
Reason: Approver of
the GxP document
Date: May 1, 2022
11:38 PDT

01-May-2022

Date

Declaration of Conformity List

Name of Device, Components, Parts and/or Accessories as per product label	Catalog Number
LABType™ HD Class I C Locus Typing Test	RSSOH1C
LABType™ HD Class I C Locus Typing Test - 20 tests	RSOH1CT
LABType™ SSO Class I C Locus Typing Test	RSSO1C
LABType™ SSO Class I C Locus Typing Test - 20 tests	RSO1CT
LABType™ SSO Class II DPA1/DPB1 Typing Test	RSSO2P
LABType™ SSO Class II DPA1/DPB1 Typing Test - 20 tests	RSO2PT
LABType™ SSO Class II DQA1/DQB1 Typing Test	RSSO2Q
LABType™ SSO Class II DQA1/DQB1 Typing Test - 20 tests	RSO2QT
LABType™ SSO MICA	RSSOMICA
PE - Conjugated Streptavidin	LT-SAPE
PE - Conjugated Streptavidin	LTSPSAPE

Note: The above products are supplied in different quantities. This distinction is designated by "X" or "T" in the catalogue identification number. If the above products are licensed this distinction is designated by "L" in front of the catalogue identification number.

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Final Audit Report

2022-05-01

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