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**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, Annex II List B

Conformity assessment  
Route: Annex IV of the IVDD (full QA System)

Certificate Registration No.: SX 60143059 0001

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

Certificate Registration No.: HL 2233216-1  
Notified Body: TÜV Rheinland LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg  
Germany

Notified Body Registration No.: 0197

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 ISO 14971:2019, EN ISO 15225:2016, EN 62366-1:2015



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Angela Estany  
Sr. Director, Regulatory Affairs & Quality Systems

Electronically signed by:  
Angela Estany  
Reason: Approver of  
the GxP document  
Date: May 1, 2022  
11:32 PDT

**01-May-2022**

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Date

This Declaration of Conformity is issued under the sole responsibility of One Lambda, Inc.

### Declaration of Conformity List

| <b>Name of Device, Components, Parts and/or Accessories as per product label</b> | <b>Catalog Number</b> |
|----------------------------------------------------------------------------------|-----------------------|
| LABType™ HD Class I A Locus Typing Test                                          | RSSOH1A               |
| LABType™ HD Class I A Locus Typing Test - 20 tests                               | RSOH1AT               |
| LABType™ HD Class I B Locus Typing Test                                          | RSSOH1B               |
| LABType™ HD Class I B Locus Typing Test - 20 tests                               | RSOH1BT               |
| LABType™ HD Class II DRB1 Typing Test                                            | RSSOH2B1              |
| LABType™ HD Class II DRB1 Typing Test - 20 tests                                 | RSOH2B1T              |
| LABType™ SSO Class I A Locus Typing Test                                         | RSSO1A                |
| LABType™ SSO Class I A Locus Typing Test - 20 tests                              | RSO1AT                |
| LABType™ SSO Class I B Locus Typing Test                                         | RSSO1B                |
| LABType™ SSO Class I B Locus Typing Test - 20 tests                              | RSO1BT                |
| LABType™ SSO Class I B7 Supplement Typing Test                                   | RSSO1S1               |
| LABType™ SSO Class I B7 Supplement Typing Test - 20 test                         | RSO1S1T               |
| LABType™ SSO Class I Bw4 Supplement Typing Test                                  | RSSO1S4               |
| LABType™ SSO Class I Bw4 Supplement Typing Test - 20 tests                       | RSO1S4T               |
| LABType™ SSO Class I Exon 4-7 Supplement Typing Test                             | RSSO1E47              |
| LABType™ SSO Class I Exon 4-7 Supplement Typing Test - 20 tests                  | RSO1E47T              |
| LABType™ SSO Class II DRB1 Typing Test                                           | RSSO2B1               |
| LABType™ SSO Class II DRB1 Typing Test - 20 tests                                | RSO2B1T               |
| LABType™ SSO Class II DRB3,4,5 Typing Test                                       | RSSO2345              |
| LABType™ SSO Class II DRB3,4,5 Typing Test - 20 tests                            | RSO2345T              |

# 2022-04-22 LABType SSO Declaration of Conformity\_Notified

Final Audit Report

2022-05-01

|                 |                                                    |
|-----------------|----------------------------------------------------|
| Created:        | 2022-04-29                                         |
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