

Date: July 24, 2023

To whom it may concern,

This letter is to certify that the attached Declaration of Conformity provided by **One Lambda, Inc.** reflecting the product name **LABScreen™**.

OLI confirms no significant changes were made to this Declaration of Conformity, signed **05May2022**. This letter is to state and clarify the follow:

1. Authorized Representative name change to MDSS GmbH
2. Addition of the Revision History page
3. Confirm Manufacturer name and address is equivalent to the Place of Issue

Regards,



*Electronically signed by:
Sheryl Skinner
Reason: Approver of the GxP
document
Date: Jul 24, 2023 21:32 EDT*

Sheryl Skinner
Director, Regulatory
One Lambda, Inc.

Revision History:

Revision Number	Revision Date	Description
Rev: 00	05May2022	Removed EN ISO 14971:2012. Added EN ISO 14971:2019
Rev: 01	16Aug2022	Changed Cert# to SX2233216-1
Rev: 02	24Jul2023	Update AR name from Medical Device Safety Service GmbH to MDSS GmbH

**Declaration of Conformity
For
LABScreen™**

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

Product: LABScreen™ - 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

LABScreen™ was 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 62366-1:2015.



Electronically signed
by: Angela Estany
Reason: Approver of
the OUP document
Date: May 5, 2022
16:32 PDT

Angela Estany
Sr. Director, Regulatory Affairs and Quality

05-May-2022

Date

Declaration of Conformity List

Name of Device, Components, Parts and/or Accessories as per product label	Catalog Number
LABScreen™ MICA Single Antigen - Group 1	LSMICA001
Below not included in the kit	
LABScreen™ Negative Control	LS-NC
PE Conjugated Goat Anti-Human IgG	LS-AB2