ONE LAMBDA
A Thermo Fisher Scientific Brand

One Lambda, Inc.
22801 Roscoe Blvd.
West Hills, CA 91304
Tel 747.494.1000
Fax 747.494.1001
www.onelambda.com

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.

Digitally signed by Ceaicovschi Tudor
Date: 2023.09.22 15:55:35 EEST
Reason: MoldSign Signature
Location: Moldova

Revision History:

Revision Number	Revision Date	Description
Rev: 00	25Nov2019	Added Catalog Number LS1AEX01 and LS2AEX01
Rev: 01	01Feb2021	Removed EN ISO 15225:16
Rev: 02	23Feb2022	Changed EC Cert# for Notified Body from HL601431290001 to HL2233216-1 Updated EN ISO 15223-1:2012 to EN ISO 15223-1:2021 Updated EN ISO 14971:2012 to EN ISO 14971:2019
Rev: 03	16Aug2022	Changed Cert# to SX2233216-1
Rev: 04	24Jul2023	Update AR name from Medical Device Safety Service GmbH to MDSS GmbH

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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, 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 Tillystraβe 2, D-90431 Nürnberg Germany
Notified Body Registration No.:	0197
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 QMP document Date: May 5, 2022 16:35 PDT

Angela Estany
Sr. Director, Quality and Regulatory Affairs

05-May-2022
Date

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

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Declaration of Conformity List

Name of Device, Components, Parts and/or Accessories as per product label	Catalog Number
LABScreen™ PRA Class I & II	LS12PRA
LABScreen™ PRA Class I	LS1PRA
LABScreen™ PRA Class I - Sample	LS1PRAS
LABScreen™ PRA Class II	LS2PRA
LABScreen™ PRA Class II - Group 1 Sample	LS2PRAS
LABScreen™ Mixed Class I & II	LSM12
LABScreen™ Mixed Class I & II - Sample	LSMS
LABScreen™ Single Antigen HLA Class I - Combi	LS1A04
LABScreen™ Single Antigen HLA Class I - Combi - Sample	LS1A04S
LABScreen™ Single Antigen HLA Class II - Group 1	LS2A01
LABScreen™ Single Antigen HLA Class II - Group 1 Sample	LS2A01S
LABScreen™ Single Antigen HLA Class I Supplement - Group 1	LS1ASP01
LABScreen™ Single Antigen HLA Class II Supplement - Group 1	LS2ASP01
LABScreen™ Single Antigen HLA Class I ExPlex	LS1AEX01
LABScreen™ Single Antigen HLA Class II ExPlex	LS2AEX01

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