

Declaration of Conformity For HLA Tissue Typing Trays

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

Product:
(attached) HLA Tissue Typing Trays - See Declaration of Conformity List

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: MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

HLA Tissue Typing Trays 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



*Electronically signed by: Sheryl
Skinner
Reason: Approver of the GxP
document
Date: Jul 19, 2023 17:27 EDT*

Sheryl Skinner
Director, Regulatory Affairs

Date

Declaration of Conformity List

Name of Device, Components, Parts and/or Accessories as per product label	Catalog Number
Terasaki HLA Tissue Typing Trays	
Terasaki HLA-C Locus Tissue Typing Tray	C72
Terasaki HLA-C Locus Tissue Typing Tray - Sample	C72S
Terasaki HLA C Locus Supplement Tissue Typing Tray	C722
Components Packaged Separately	
Class I Complement - 5 ml	CABC-5
Class I Complement - 50 ml	CABC-50
Lyophilized Class I Complement	CABC-1D
Class II Complement - 5 ml	CDR-5
Class II Complement - 50 ml	CDR-50
Lyophilized Class II Complement	CDR-1D

Revision History:

Revision Number	Revision Date	Description
Rev: 00	05May2022	Removed EN ISO 14971:2012. Added EN ISO 14971:2019
Rev: 01	11Jul2023	Update AR name from Medical Device Safety Service GmbH to MDSS GmbH