

Declaration of Conformity For HLA Tissue Typing Trays

Manufacturer: 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, 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

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: 2012, EN ISO 13485:2016, EN 13612:2002, EN ISO 23640:2015, EN 13641:2002, EN 13975:2003, EN 14136:2004, EN ISO 14971:2012, EN ISO 15225:2016, EN 62366-1:2015



Electronically signed by:
Geeth Vijay-Rao
Reason: Approver of the
GxP document
Date: Feb 24, 2022 09:34
PST

24-FEB-2022

Geeth Vijay-Rao
Sr. Manager, 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 Class I ABC Tissue Typing Tray - (A)	TS144A
Terasaki HLA Class I ABC Tissue Typing Tray - (B)	TS144B
Terasaki HLA Class I Tissue Typing Tray Set	TM144
Terasaki Class I Tissue Typing Tray Set	TM144S
Terasaki HLA Class I Tissue Typing Tray Set (A)	TM144A
Terasaki HLA Class I Tissue Typing Tray Set (B)	TM144B
Terasaki HLA-A Locus Supplement Tissue Typing Tray	AS72
Terasaki HLA-A Locus Supplement Tissue Typing Tray - Sample	AS72S
Terasaki HLA-ABC First Tissue Typing Tray	T1-72
Terasaki HLA-ABC First Tissue Typing Tray - Sample	T1-72S
Terasaki HLA-ABC Oriental Tissue Typing Tray	OT-72
Terasaki HLA-ABC Oriental Tissue Typing Tray - Sample	OT-72S
Terasaki HLA-ABC Second Tissue Typing Tray	T2-72
Terasaki HLA-ABC Second Tissue Typing Tray - Sample	T2-72S
Terasaki HLA-ABC Third Tissue Typing Tray	T3-72
Terasaki HLA-ABC Third Tissue Typing Tray - Sample	T3-72S
Terasaki HLA-B Locus Supplement Tissue Typing Tray	BS72
Terasaki HLA-B Locus Supplement Tissue Typing Tray - Sample	BS72S
Terasaki HLA-B27 Chinese Dry Tissue Typing Tray - 3-test tray	27-03CD
Terasaki HLA-B7/40 Locus Supplement Tissue Typing Tray - Sample	BS740-72S
Terasaki HLA-B7/40 Supplement Tissue Typing Tray	BS740-72
Terasaki HLA Class I and Class II Dry Tissue Typing Trays	
Terasaki HLA Class I Asian Dry Tissue Typing Tray	ASN72D
Terasaki HLA Class I Asian Dry Tissue Typing Tray - Sample	ASN72DS
Terasaki HLA Class I Dry Tissue Typing Tray	AB72D
Terasaki HLA Class I Dry Tissue Typing Tray - Sample	AB72DS
Terasaki HLA Class II Dry Tissue Typing Tray	DR72D
Terasaki HLA Class II Dry Tissue Typing Tray - Sample	DR72DS
Terasaki HLA-B27 Dry Tissue Typing Tray - 6-test tray	27-06D
Terasaki HLA Class II Tissue Typing Tray	DR72
Terasaki HLA Class II Tissue Typing Tray - Sample	DR72S
Lambda Monoclonal HLA Class I and Class II Tissue Typing Trays	
Lambda Monoclonal Trays™ Set HLA Class I (A,B) - 2-tray set	LM144

Name of Device, Components, Parts and/or Accessories as per product label	Catalog Number
Lambda Monoclonal Trays™ Set HLA Class I (A)	LM144A
Lambda Monoclonal Trays™ Set HLA Class I (B)	LM144B
Lambda Monoclonal Trays™ Set HLA Class I (A,B) - 2-tray set - Sample	LM144S
Lambda Monoclonal Trays™ First HLA Class I	LM172
Lambda Monoclonal Trays™ First HLA Class I - Sample	LM172S
Lambda Monoclonal Trays™ Second HLA Class I	LM272
Lambda Monoclonal Trays™ Second HLA Class I - Sample	LM272S
Lambda Monoclonal Trays™ Third HLA Class I	LM372
Lambda Monoclonal Trays™ HLA Class I (Oriental)	LM72OR
Lambda Monoclonal Trays™ HLA Class I - 96 well	LM96
Lambda Monoclonal Trays™ HLA B27 tray	LMB2701
Lambda Monoclonal Trays™ HLA B27 tray - Sample	LMB2701S
Lambda Monoclonal Trays™ HLA B27 tray (3 test/tray)	LMB2703
Lambda Monoclonal Trays™ HLA B27 tray (3 tray/test) - Sample	LMB2703S
Lambda Monoclonal Trays™ HLA Class I (Black)	LMBL72
Lambda Monoclonal Trays™ First HLA Class II - 60 well	MDR160
Lambda Monoclonal Trays™ First HLA Class II - 60 well - Sample	MDR160S
Lambda Monoclonal Trays™ First HLA Class II	MDR172
Lambda Monoclonal Trays™ First HLA Class II - 72 well - Sample	MDR172S
Lambda Monoclonal Trays™ Second HLA Class II	MDR272
Lambda Monoclonal Trays™ Second HLA Class II - 72 well - Sample	MDR272S
Lambda Monoclonal Trays™ Set HLA Class I	2LM72
Fast Monoclonal Tray	
Fast Monoclonal Trays™ Class II	FTDR72