

Declaration of Conformity for Adsorb Out™

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

Product: Adsorb Out™ (ADSORB)

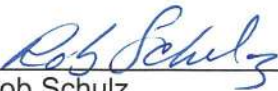
Classification: IVDD, Non Annex II, Self – Declaration

Conformity assessment
Route: Annex III (EC Declaration of Conformity)

We, the manufacturer, herewith declare that the above mentioned products are in conformance with the legislation of the Member State for which our Notified Body is located and complies with the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Authorized Representative: Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover
Germany

Absorb Out™ was 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, EN13975:2003, EN 14136:2004,
EN ISO 14971:2012, EN ISO 15225:2016, EN 62366-1:2015.



Rob Schulz
Sr Manager, Regulatory Affairs



Date