GOLD STANDARD DIAGNOSTICS

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	**Model/Number**
ThunderBolt® EIA, ThunderBolt® EIA-CL	Models: 00300, 00300-CL

MANUFACTURER		
Name of Company	**Address**	**Representative**
Gold Standard Diagnostics Corp.	2795 2nd Street Davis, CA 95618 USA	Tony Sanford

AUTHORIZED REPRESENTATIVE		
Name of Company	**Address**	**Telephone/Email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

CONFORMITY ASSESSMENT		
Device Classification	**Route to Compliance**	**Standards Applied**
Class: Self-Certify	Annex III of IVDD 98/79/EC Council Directive	Directive 98/79/EC of the European Parliament and of the Council on IVD Medical Devices
Electronic Equipment for Measurement, Control, and Laboratory Use		IEC 61010-1:2010 (3rd Edition); ANSI/UL 61010-1:2012; CAN/CSA-C22.2 No. 61010-1:2012 (3rd Edition)
Electronic Equipment for Measurement, Control, and Laboratory Use for In Vitro Diagnostic (IVD)		IEC 61010-2-101:2015; ANSI/UL 61010-2-101:2015; CAN/CSA-C22.2 No. 61010-2-101:2015
Electromagnetic Compatibility (EMC) – Electrical Equipment for Measurement, Control and Laboratory Use		EN 61326-1:2013; EN 61326-2:2013; FCC Part 15, Subpart B
Interference Causing Equipment (ICE) – Health Canada		ICES-003 Information Technology Equipment (ITE) – Limits and methods of measurement.
Restriction on Hazardous Substances (RoHS)		EN/IEC 62321-3-1:2014 EN/IEC 62321-6:2015 EN 50581:2012 RoHS 2011/65/EU

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Gold Standard Diagnostics Corp. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Tony Sanford

TITLE: VP Quality & Regulatory **SIGNATURE:** 

DATE: 4-28-2021