Lin-Zhi International, Inc.

EC DECLARATION OF CONFORMITY: LZI Drug of Abuse Urinalysis Products

Declaration of Conformity No. 2021-001-U (Beckman)

In accordance with Directive 98/79/EC on *in vitro* diagnostic medical devices, Annex III and ISO/IEC 17050-1

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Product Name	Product Reference Number	GMDN Code	First Date of CE-Compliance
Buprenorphine, EIA Kit, R_1 & R_2 (2 x 100 tests)	A53684	42751	2015-06-24
Norbuprenorphine Negative Calibrator (0 ng/mL)	A53687	42691	2015-06-24
Norbuprenorphine Low Calibrator (5 ng/mL)	A68826	42691	2015-06-24
Norbuprenorphine Control Level 1 (7 ng/mL)	A68824	42760	2015-06-24
Norbuprenorphine Cutoff Calibrator (10 ng/mL)	A68827	42691	2015-06-24
Norbuprenorphine Control Level 2 (13 ng/mL)	A68825	42760	2015-06-24
Norbuprenorphine Intermediate Calibrator 1 (20 ng/mL)	A68828	42691	2015-06-24
Norbuprenorphine Intermediate Calibrator 2 (40 ng/mL)	A68829	42691	2015-06-24
Norbuprenorphine High Calibrator (100 ng/mL)	A68830	42691	2015-06-24
LZI Universal Negative Calibrator	C68807	55460	2021-01-04
LZI Norfentanyl Level 1 Control (3.75 ng/mL), 5 mL	C68821	55631	2021-01-04
LZI Norfentanyl Level 2 Control (6.25 ng/mL), 5 mL	C68822	55631	2021-01-04
LZI Fentanyl Enzyme Immunoassay, small test kit	C68809	63018	2021-01-04
LZI Norfentanyl Qualitative Calibrator (5 ng/mL), 5 mL	C68810	55630	2021-01-04
LZI Norfentanyl Semi-Quantitative Calibrator Set	C6811	55630	2021-01-04
LZI Hydrocodone EIA Kit	C68823	55717	2021-01-04
LZI Hydrocodone 300 Qualitative Calibrator (300 ng/mL), 5 mL	C68830	55722	2021-01-04
LZI Hydrocodone 300 Semi-Quantitative Calibrator Set	C68831	55722	2021-01-04
LZI Hydrocodone 300 Level 1 Control (225 ng/mL), 5 mL	C68828	55723	2021-01-04
LZI Hydrocodone 300 Level 2 Control (375 ng/mL), 5 mL	C68829	55723	2021-01-04
LZI Ketamine EIA Kit, small test kit	C68802	62129	2021-01-04
LZI Norketamine Qualitative Calibrator (50 ng/mL), 5 mL	C68804	62131	2021-01-04
LZI Norketamine Semi-Quantitative Calibrator Set	C68803	62131	2021-01-04
LZI Norketamine Level 1 Control (37.5 ng/mL), 5 mL	C68805	62132	2021-01-04
LZI Norketamine Level 2 Control (62.5 ng/mL), 5 mL	C68806	62132	2021-01-04

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Classification: Other devices (all devices except Annex II and self-testing devices)

We declare that the above mentioned products meet the provisions of the council directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Lin-Zhi International, Inc. **considers the following laws, rules and standards:**

• IVDD 98/79/EC	European Economic Area (EEA) *in vitro* diagnostics directive
• EN ISO 13485:2016	Medical devices quality management systems requirements for regulatory purposes
• EN 13612:2002	Performance evaluation of *in vitro* diagnostic medical devices
• EN ISO 14971:2012	Application of risk management to medical devices
• EN ISO 15223-1:2016	General Requirements - Symbols to be used with medical device labels, labelling, and information to be supplied
• EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
• EN-ISO/1EC 17050-1:2010	Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements
• EN ISO 18113:2011 *(Parts 1, 2, 3)*	*In vitro* diagnostic medical devices – Information supplied by the manufacturer (labeling)
• EN ISO 15193:2009	*In vitro* diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for content and presentation of reference measurement procedures
• EN ISO 15194:2009	*In vitro* diagnostic medical devices – Measurement of quantities in samples of biological origin – Requirements for certified reference materials and the content of supporting documentation
• EN ISO 17511:2003	*In vitro* diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials
• EN ISO 23640:2015	*In vitro* diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents

Approved By: _____ Date: January 04, 2021

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