

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product Name	Model/Number
BreathTracker SC, 230V/50Hz	QT05001-M
BreathTracker DP, 230V/50Hz	QT05003-M
BreathTracker H2+, 230V/50Hz	QT05005-M
BreathTracker H2, 230V/50Hz	QT05007-M
AlveoVac Extraction System, 24VDC (EU Plug)	QT05201-M
AlveoVac Extraction System, 24VDC (UK Plug)	QT05204-M
AlveoSampler Kit (No Substrate)	QT00827-P
GaSampler Single-Patient Kit, No Substrate	QT00892
GaSampler Single-Patient Collection Bag (750mL for Adult/Pediatric)	QT00830-P
GaSampler Tee-Mouthpiece Assembly	QT00854-P
GaSampler 400mL Discard Bag	QT00843-P
Low-Deadspace, One Way Sampling Valve, Pediatric	QT00859-P
EasySampler Device Only	QT00815-P
Fructose Malabsorption EasySampler Kit	QT04204
Lactose Malabsorption EasySampler Kit	QT04206
EasySampler, No Substrate (10 Tubes)	QT04207
EasySampler, No Substrate (4 Tubes)	QT04208
Lactulose - Small Intestinal Bacterial Overgrowth (SIBO) EasySampler Kit	QT04205
Glucose - Small Intestinal Bacterial Overgrowth (SIBO) EasySampler Kit	QT04210
d-Xylose EasySampler Kit	QT04203
Sucrose Malabsorption EasySampler Kit	QT04214
Glucose/Dextrose, 100gm/packet (Unflavored)	QT02300-100-S
Glucose/Dextrose, 75gm/packet (Unflavored)	QT02300-75-S
LacTest®, Lactose, 25gm/packet (Orange Flavored)	QT02425-S
Lactulose, 10gm/15ml syrup (Cherry Flavored)	QT02500-10-S
d-Xylose, 25gm/packet (Unflavored)	QT02700-25-S
Fructose, 25gm/packet (Unflavored)	QT02900-25-S
Sucrose, 50gm/packet (Unflavored) (1/Each)	QT02600-50-S
SivRite-4 Room-Air Conditioning Desiccant (BreathTracker)	QT01154-C
Desiccant, BreathPrep™	QT01161-C
Patient Sample Drying Tube	QT01135-K
Dust Barrier (5/Pack)	QT01140-K

PRODUCT IDENTIFICATION CONTINUED

Foam Filter Plug (10/Pack)	QT00527-T
SamplXtractor - Model SX-2 Plus - Maintenance Kit	QT02687
AlveoVac/SamplXtractor Plastic Vial Adapters (5/Pack)	QT02688
Tubing, Output, Extraction System (AlveoVac)	QT02704
SivRite-4 Tubing Assembly	QT02509
1-Way Plastic Stopcock, Single-Patient	QT01727-V
30ml Plastic Syringe, Luer Lock (Non-Sterile), Single-Patient	QT02741
250ml, Sample Holding Bag, Single-Patient	QT00842-P
Plastic, Mouthpiece, 20mm	QT00991-P
Tee-Connector, Plastic	QT00850-P
Flutter Valve, One-Way, For Tee-Connector	QT00851-P
AlveoSampler Bag Only	QT01090
QuinGas, BreathTracker Calibration	QT07500-G
QuinGas-2, MicroLyzer Calibration	QT07300-G
Tank, Support, Safety, Table-Top	QT02773
Regulator/Pressure Gauge, QuinGas	QT02772
AlveoVac Vials, 3 Pack	QT02633
AlveoVac Vials, 4 Pack	QT02634
AlveoVac Vials, 5 Pack	QT02635
AlveoVac Vials, 100/Box (Bulk)	QT02602

MANUFACTURER

Name of Company	Address	Representative
QuinTron Instrument Company, Inc.	2208 South 38 th Street Milwaukee, Wisconsin 53215 USA	Katherine Ross, Quality Management Representative

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	ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
		IEC 60601-1:1988-Ed.2.0 IEC 60601-1:1988-Ed.2.0/Amd.1:1991 IEC 60601-1:1988-Ed.2.0/Amd.2:1995	Medical electrical equipment - Part 1: General requirements for basic safety
		IEC 60601-1-2:2014-Ed.4.0	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
		CSA C22.2 NO. 601.1 M90 (R2006)	Medical electrical equipment - Part 1: General requirements for safety (adopted amendment 2:1995 to IEC 601-1:1990)
		CLSI EP5-A2:2004	Evaluation of precision performance of quantitative measurement methods; Approved guideline
		CLSI EP6-A:2003	Evaluation of the linearity of quantitative measurement procedures: A statistical approach; Approved guideline
		EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
		IEC 62304:2006/Amd 1:2015	Medical device software – software life cycle processes
		IEC 61000-4-2:2008-Ed.2.0	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
		IEC 61000-4-3:2010-Ed.3.2	Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
		IEC 61000-4-4:2012	Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test
		IEC 61000-4-5:2014	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques Surge immunity test
		IEC 61000-4-6:2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

		IEC 61000-4-8:2009-Ed.2.0	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
		IEC 61000-4-11:2004-Ed.2.0	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
		IEC 61000-3-2:2005 + A1:2008 + A2:2009	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤16 A per phase) TPS Listing: IEC 61000-3-2:2009-Ed.3.2/Cor.1:2009
		IEC 61000-3-3:2008-Ed.2.0	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16A per phase and not subject to conditional connection
		IEC 61326-1:2012-Ed.2.0	Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements TPS Listing: IEC 61326-1:2005-Ed.1.0/Cor.1:2008
		IEC 61326-2-6:2012-Ed.2.0	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
		IEC CISPR 11:2009+A1:2010	Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement
		GHS – 2011 – Fourth revised edition	Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

QuinTron Instrument Company, Inc. 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: Katherine Ross

TITLE: Management Representative

SIGNATURE:

DATE: 2019/01/21

