



Test Report issued under the responsibility of:



TEST REPORT
IEC 61010-1
Safety requirements for electrical equipment for measurement,
control, and laboratory use
Part 1: General requirements

Report Number..... : 31882348.001
Date of issue..... : December 06, 2018
Total number of pages : 120

Applicant's name : Hygiena, LLC
Address..... : 941 Avenida Acaso, Camarillo, CA 93012, USA

Test specification:
Standard..... : IEC 61010-1:2010 (Third Edition)
Test procedure : CB Scheme
Non-standard test method : N/A

Test Report Form No. : IEC61010_1J
Test Report Form(s) Originator : VDE Testing and Certification Institute
Master TRF..... : 2013-11

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Test item description..... : Hand Held Bio Tester
Trade Mark..... : 
Manufacturer : Same as Applicant
Model/Type reference : EnSURE Touch
Ratings : N/A

Testing procedure and testing location:		
<input checked="" type="checkbox"/>	Testing Laboratory:	TUV Rheinland of North America, Inc.
Testing location/ address		295 Foster Street, Suite 100, Littleton, MA 01460, USA
<input type="checkbox"/>	Associated Laboratory:	
Testing location/ address		
	Tested by (name + signature)	Chansophon Sim 
	Approved by (name + signature)	John Coviello 
<hr/>		
<input type="checkbox"/>	Testing procedure: TMP	
Testing location/ address		
	Tested by (name + signature)	
	Approved by (name + signature)	
<hr/>		
<input type="checkbox"/>	Testing procedure: WMT	
Testing location/ address		
	Tested by (name + signature)	
	Witnessed by (name + signature)	
	Approved by (name + signature)	
<hr/>		
<input type="checkbox"/>	Testing procedure: SMT	
Testing location/ address		
	Tested by (name + signature)	
	Approved by (name + signature)	
	Supervised by (name + signature)	
<hr/>		
<input type="checkbox"/>	Testing procedure: RMT	
Testing location/ address		
	Tested by (name + signature)	
	Approved by (name + signature)	
	Supervised by (name + signature)	

List of Attachments (including a total number of pages in each attachment)		
Document No.	Documents included / attached to this report (description)	Page No.
Attachment 1	List of components and circuits relied on for safety	80-81
Attachment 2	Summary of Group & National Differences	82-108
Attachment 3	Photographs	109-117
Attachment 4	Agency Approval Licenses	118-120

Documents referenced by this report (available on request):		
Document Name or No.	Documents description	Page No.
None referenced.		

Test Report History:

This report may consist of more than one report and is valid only with additional or previous issued reports:

Tests performed (name of test and test clause):

31882348.001:

Date of receipt of test item: 8/21/2018

Date(s) of performance of tests: 9/10/18-9/13/18, 12/6/2018

Outputs (4.4.2.8)

Durability of Markings (5.3)

Sharp edges (7.2)

Static test (8.2.1)

Hand-held equipment (8.3.2)

Equipment and Direct Plug-in Equipment

Temperature limits and resistance to heat (10)

Testing location:

TUV Rheinland of North America, Inc.

295 Foster Street Suite 100

Littleton, MA 01460, USA

Summary of compliance with National Differences

List of countries addressed: Switzerland, CA, US Group Differences.

Explanation of used codes: CA = Canada, US = United States of America.

The product fulfils the requirements of EN 61010-1:2010 (Third Edition), CSA C22.2 No. 61010-1-12 / UL 61010-1:2012

Electromagnetic Compatibility Test Report

Description: Advanced Monitoring System
with 5V DC USB Charger




Model: Hygiena EnSURE™ Touch with with
TEN PAO International S008ACM0500150

Hygiena LLC
941 Avenida Acaso
Camarillo, CA 93012

Prepared by:

TUV Rheinland of North America, Inc.

Report No.: 31862100.004
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Client:	Hygiena LLC 941 Avenida Acaso Camarillo, CA 93012	Contact: Tel: Fax: e-mail:	Ed Ott John Fayos Ed 408-202-9852 John 315-425-4045 - edward.ott@sanmina.com john.fayos@sanmina.com
Identification:	Advanced Monitoring System	Serial No.:	Not serialized
Test item:	Hygiena EnSURE™ Touch with 5V DC USB Charger	Date Test Completed:	10/09/2018
Testing location:	TUV Rheinland of North America 710 Building 199, Resende Road Webster, NY 14580 U.S.A.	Tel: (585) 645-0125 Fax: -	
Test specification:	Emissions: ETSI EN 301 489-1 V2.1.1, and ETSI EN 301 489-17 V3.1.1 EN 61326-1:2013 EN 55011:2009+A1:2010, FCC Part 15 Subpart B:2018, AS/NZ CISPR11:2015 +A1:2016 +A2:2019, ICES-003 Issue 6 EN61000-3-2:2014, EN61000-3-3:2013 Immunity: EN 61326-1:2013, EN61000-4-2:2009, EN61000-4-3:2006: +A1:2008 + A2:2010, EN61000-4-4:2012, EN61000-4-5:2006, EN61000-4-6:2009, EN61000-4-8:2010, EN61000-4-11:2004		
Test Result and/or Conclusion:	The above product was found to be Compliant to the above test standard(s)		
Report written/updated by: Amy E Hunnewell-Fitzroy		reviewed by: David Spencer	
20 March 2020 <i>Amy E Hunnewell-Fitzroy</i> Date Signature		20 March 2020 <i>David Spencer</i> Date Signature	
			
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Ref. Certif. No.

US-TUVR-011431

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

CB TEST CERTIFICATE

Product

Hand Held Bio Tester

Name and address of the applicant

Hygiena LLC
941 Avenida Acaso
Camarillo CA 93012, USA

Name and address of the manufacturer

Hygiena LLC
941 Avenida Acaso
Camarillo CA 93012, USA

Name and address of the factory

Sanmina Corporation
2417 South 3850 West
Salt Lake City UT 84120, USA

Ratings and principal characteristics

Class III

Trademark (if any)

hygiena

Customer's Testing Facility (CTF) Stage used

Model / Type Ref.

EnSURE Touch

Additional information (if necessary may also be reported on page 2)

CA, US

A sample of the product was tested and found to be in conformity with

IEC 61010-1:2010
for national deviations see test report

As shown in the Test Report Ref. No. which forms part of this Certificate

31882348 001

This CB Test Certificate is issued by the National Certification Body



TUV Rheinland of North America, Inc.
12 Commerce Road
Newtown, CT 06470 - USA

Date: 10.12.2018

Signature:  Martin Glagla