



DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer as stated below

Legal Manufacturer's Name:

Universal Biosensors Pty Ltd

Legal Manufacturer's Address:

1 Corporate Avenue
Rowville
Victoria, Australia 3178

The object of this declaration is the following product:

Product Name	Product Code
Sentia™ Analyzer	79001
Sentia™ Free Sulfur Dioxide Test Strips	71007

Applicable Directives & Regulations:

Stated object of this declaration as above is in conformity with the following regulations and standards:

European Union (CE Marking):

- Directive **2014/35/EU** of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
The conformity assessment route to comply with this directive is Annex III
Harmonised standards applied
- Directive **2014/30/EU** of the European Parliament and of the council 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility
The conformity assessment route to comply with this directive is Annex II
- Directive **2014/53/EU** of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC
The conformity assessment route to comply with this directive is Annex II
- Directive **2011/65/EU** of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
This declaration confirms that the above listed product to best of our knowledge does not contain hazardous substances as determined via external testing



The following Harmonised standards applied

- ETSI 300 328
- IEC 61326-1
- ETSI EN 301 489-1
- ETSI EN 301 489-17
- IEC 61010-1
- EN IEC 61000-3-2
- EN 61000-3-3
- EN 50663
- EN 62479
- EN IEC 6300
- EN 55032
- EN 55024
- IEC 62368

European Union (Non - CE Marking):

- Regulation (EC) **No 1907/2006** of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
Declaration confirms that the device does not contain SVHC (substances of very-high concern)
- Directive **2012/19/EU** of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
Declaration confirms that the Electrical equipment is recyclable under WEEE

Battery component of the above product 79001 conforms to

- UN 38.3 UN Recommendations on the Transport of Dangerous Goods, Manual of Test and Criteria
- UL/IEC 62133 (Standard For Safety For Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications)
- Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC

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Australia:

- Radiocommunications (compliance labelling - devices notice 2014)
- Radiocommunication Labelling (EMC) Notice 2017
- Radiocommunications (Compliance Labelling—EMR) Notice 2014
- ACMA/EESS requirements in accordance with AS/NZS 4417.1
- Environment protection Act 1970 Waste Management Policy (E-waste) product stewardship Act 2011

Standards applied

- AS/NZS 4268
- IEC 61326
- ARPANSA RPS
- AS/NZS 2772.2
- NZS 2772.1
- EN 50663
- EN 62479
- IEC 61010-1
- CISPR 22
- CISPR 14.1
- IEC 62368 (safety)

New Zealand:

- RSM Guidelines
- Radiocommunications Regulations notice 2019
- Electricity regulations 2010
- Product Stewardship scheme - Hazardous substances and New organisms (HSNO) Act 1996

Standards applied

- CISPR 14.1
- AS/NZS 2772.2
- ARPANSA RPS
- EN 50663
- EN 62479
- IEC61010-1

United States of America (USA):

- 47 CFR (FCC) Part 2 – Frequency Allocations and Radio treaty matters, General Rules and Regulations
- 47 CFR (FCC) Part 15 – Radio Frequency Devices
- IEEE C95.1 IEEE Standard for Safety Levels with Respect to Human Exposure to Electric, Magnetic, and Electromagnetic Fields, 0 Hz to 300 GHz
- The consumer product safety improvement Act (CPSIA)
- OSHA Part 1910 of Title 29, Code of federal regulations - 29 CFR Part 1910
- 10 CFR 430 Energy conservation program for consumer products

Standards applied

- IEC 61010-1
- IEC 62368
- 10 CFR 430 Energy conservation program for consumer products
- California Proposition 65 (The Safe Drinking Water and Toxic Enforcement Act of 1986)

This declaration confirms that the device does not contain any hazardous substance described in the above Act.

Canada:

- Radio Standards Specifications requirements
- Specific Absorption rate requirements

Standards applied

- RSS-GEN
- RSS-102
- RSS-247
- IEEE-1528
- IEC 62209-1
- IEC 62209-2

We, the manufacturer, herewith declare that the stated device meets the provisions of Directives Regulations and Standards listed above.

Place and Date of Declaration:

Place: Melbourne

Date: 19 May 2021

Signed for and on behalf of Universal Biosensors Pty Ltd



Signature:

Name: Nicholas Bliesner

Position: Head of Operations

Universal Biosensors Pty Ltd.