



**Declaration of Conformity for Medical Devices**

**According to Annex IX of the Council Directive 93/42/EEC for Medical Devices.**

**Manufacturer:**

**pixel-town OHG  
Am Pfarrgarten 7  
D-50259 Pulheim-Stommeln  
Germany**

We declare that the following product is manufactured by our sole responsibility:

**Name:**

**BiteStrip Electronic Bruxism Sensor**

**REF: 1000/1200  
Medical Product Class: I**

is in accordance with the Council Directive 93/42/EEC for Medical Devices.  
The Technical Documentation is being kept at the above mentioned address.



This declaration is valid for all deliveries after the date of issue.

Pulheim-Stommeln, 01.06.2012

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Date and Place of Issue



**pixel-town OHG**  
Am Pfarrgarten 7  
50259 Pulheim-Stommeln  
Tel: 49-221-9742833  
Fax: 49-221-9742832  
www.pixel-town.com

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Manufacturer  
André Bausch



**EG-Konformitätserklärung für Medizinprodukte**

**Gemäß Anhang IX der EG-Richtlinie 93/42/EWG für Medizinprodukte**

**Wir der Hersteller:**

**pixel-town OHG  
Am Pfarrgarten 7  
D-50259 Pulheim-Stommeln  
Germany**

erklären in eigener Verantwortung, dass das von uns hergestellte Produkt:

**Bezeichnung:**

**BiteStrip Bruxismusindikator**

**REF: 1000/1200  
Medizinprodukt der Klasse: I**

den einschlägigen Bestimmungen der Richtlinie 93/42/EWG für Medizinprodukte entspricht.

Die Technische Dokumentation wird unter obiger Anschrift aufbewahrt.



Diese Erklärung gilt für alle Lieferungen nach dem Ausstellungsdatum.

Pulheim-Stommeln, 01.06.2012

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Ort und Datum der Ausstellung

 **pixel-town OHG**  
Am Pfarrgarten 7  
50259 Pulheim-Stommeln  
Tel: 49-221-9742833  
Fax: 49-221-9742832  
www.pixel-town.com

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Sicherheitsbeauftragter  
André Bausch

## **1. Electric Bruxism Sensor**

### **1.1 Electronic Bruxism Sensor**

**Name of product:** BiteStrip

**Product/Order No.:** 1000 1 piece

**Product/Order No.:** 1200 3 pieces

#### **Description of product:**

Disposable detector for bruxism.

#### **Classification:**

Non-Invasive device for short term use. Class I product according to the European Council Directive 93/42/EEC, Annex IX, III, 3.4, Rule 12  
(active diagnostic device - for non vital body functions)

Universal Medical Device Nomenclature System: Myograph (12-692)

#### **Technical Data:**

ingredients:	electronic parts, battery, EMG-Gel, plastic cover
inflammability:	not flammable
garbage handling:	no domestic waste, recycling for used electronic devices
storage conditions:	dry and cool, room temperature

#### **Package:**

1000 1 piece

1200 3 pieces

#### **Indications for Use:**

The BiteStrip is intended as an aid in the evaluation of excessive nocturnal jaw muscle activity.

# SONY

Sony Energy Devices Corporation

1-1, Shimosugishita, Takakura, Hiwada-machi, Koriyama-shi, Fukushima 963-0531 JAPAN

Phone: 81-24-958-6376

Fax: 81-24-958-5897

Date: October 14, 2004

## Certification of "Non-Dangerous Goods"

We hereinafter certify that the following cells are considered as "non-dangerous goods".

Lithium batteries containing no more than 1g/cell and 2g/battery of lithium can be treated as "non-dangerous goods" under the United Nations recommendations on the Transport of Dangerous Goods, Special Provision 188, provided that packaging is strong and prevent the products from short-circuit.

With regard to air transport, the International Civil Aviation Organization (ICAO) Special Provision A45 accepts the above UN Recommendation as is; further, the International Air Transport Association (IATA) adopts ICAO Provision A45. In addition, the regulations of the US Department of Transportation for land, sea and air transportation are based on the UN Recommendations.

The following lithium cells/batteries fulfill the Lithium contents of the UN Recommendations on the Transport of Dangerous Goods, Special Provision 188 (ICAO Special Provision A45) and can be treated as "non-dangerous goods".

IDENTITY Product Category:

Brand:

Model Name :

(Nominal Capacity, The mass of Lithium)

Manganese Dioxide Lithium Cell

SONY

CR1216 (30mAh, 0.009g)

CR1220 (40mAh, 0.011g)

CR1616 (57mAh, 0.017g)

CR1620 (75mAh, 0.020g)

CR2016 (90mAh, 0.026g)

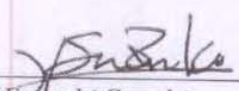
CR2025 (160mAh, 0.045g)

CR2032 (220mAh, 0.062g)

CR2430 (280mAh, 0.082g)

CR2450 (600mAh, 0.170g)

CR2477 (1,000mAh, 0.280g)

  
Hiroyuki Suzuki

AB Quality Assurance Section

AB Engineering Division

Sony Energy Devices Corporation

## Article Safety Data Sheet - Lithium Batteries <sup>1)</sup>

Edition date: January 26, 2010  
Version: 2010-01-26

RENATA SA  
 Kreuzenstrasse 30  
 CH-4452 ITINGEN / Switzerland  
 Tel: +41 61 975 75 75  
 Fax: +41 61 975 75 95

### Section I - Product identification

Product Name: **Primary (non-rechargeable) Lithium Battery** Nominal Voltage: 3.0 V  
 Models: **Coin Type Cells CR Series see Annex I**  
 Chemical System: **Lithium Manganese Dioxide (Li + MnO<sub>2</sub> → LiMnO<sub>2</sub>)**  
 Primary **NOT** designated for Recharge

### Section II - Hazardous ingredients

IMPORTANT NOTE: The battery should not be opened or exposed to heat because exposure of the following ingredients contained within could be harmful under some circumstances.

Chemical Name	CAS No.	Content % of total weight
Manganese Dioxide (MnO <sub>2</sub> )	1313-13-9	17 - 48
Lithium*	7439-93-2	1.1 - 3.3
Propylene Carbonate (PC)	108-32-7	3 - 9
1,2 dimethoxy ethane (DME)	110-71-4	1 - 3.5
Lithium Perchlorate (LiClO <sub>4</sub> )	7791-03-9	0.2 - 0.8

\* Approximate weight content of lithium in each model can be found in Annex I


#### 1) This Article Safety Data Sheet is provided as a service to our customers.

Based on the definition of the term 'article' in the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, 29 CFR Subpart 1910.1200, there is no requirement for a Material Safety Data Sheet (MSDS) for lithium primary coin cells. Notification is not required because these products are 'articles' that do not release a covered toxic chemical under the normal conditions of processing or use.

#### Disclaimer:

The batteries are exempt articles and are not subject to hazard Communication Standard Requirement. This sheet is provided as technical information only. The information contained in this Product Safety Data Sheet has been established to the best of RENATA SA's knowledge and belief. RENATA SA makes no representation and provides no warranty or guarantee regarding the contents of this Product Safety Data Sheet and excludes its liability, express or implied.

Renata SA  
 CH-4452 Itingen/Switzerland  
 Tel. +41 (0)61 975 75 75  
 Fax. +41 (0)61 975 75 95  
 sales@renata.com  
 www.renata.com

A COMPANY OF THE  SWATCH GROUP

The information and recommendations set forth are made in good faith and believed to be accurate as of the date of preparation. RENATA S.A. makes no warranty, expressed or implied, with respect to this information and disclaims all liabilities from reliance on it.

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### Section III - Possible Hazards

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The chemicals mentioned in Section II are contained in a sealed can.  
Risk of exposure occurs only if the battery is mechanically or electrically abused  
(see Safety precautions in Section VII).

The most likely risk is acute exposure when a cell vents.  
DME is believed to be slightly to moderately toxic, PC moderately toxic.  
LiClO<sub>4</sub> is irritating to skin, eyes and mucous membranes.  
Lithium can cause thermal and chemical burns upon contact with the skin.  
**Contact with electrolyte and extruded lithium with skin and eyes should be avoided.**

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### Section IV - First Aid Procedures

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**None** unless internal material exposure.

Skin contact:

Skin contact with contents of an opened battery can cause irritation, flush immediately with copious amounts of water. Remove contaminated clothing. If irritation persists, get medical help

Eye contact:

Contents of an opened battery can cause severe irritation, flush immediately thoroughly with copious amounts of water for at least 15 minutes. Get medical attention immediately.

Inhalation:

Do not inhale leaked material. Provide immediately fresh air, if irritation persists, get medical help.

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### Section V - Fire Fighting Instructions

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Flash point of electrolyte solvents (°C): DME: -6°C, PC: 123°C **Mixture: 20°C**

Extinguishing Media:

see Special Fire Fighting Procedure

Flammable Limits:

Not available

Special Fire Fighting Procedure:

In case of fire in an adjacent area, use water, CO<sub>2</sub> or dry chemical extinguishers if cells are packed in their original containers since the fuel of the fire is basically paper products.

For bulk quantities of unpackaged cells use for example LITH-X (Graphite Base). In this case, do not use water.

In a small room, remember that the supply of oxygen is quickly consumed in feeding a lithium fire.

As with any fire, wear self-contained breathing apparatus to avoid inhalation of hazardous decomposition products.

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### Section VI - Accidental Release

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Steps to be taken in case material is released or spilled:

The preferred response is to leave the area and allow the batteries to cool and the vapours to dissipate. Avoid skin and eye contact or inhalation of vapours. Collect all released material in a plastic lined metal container and remove spilled liquid with absorbent. Doing this, protect your skin and eyes with gloves and protection glasses. Avoid direct contact with internal components.

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## Section VII - Handling and Storage

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When used correctly, lithium batteries provide a safe and dependable source of power. However, if they are misused or abused, leakage, venting, or in extreme cases explosion and/or fire may result.

Make sure to observe amongst others, following warnings.

### Handling:

- Do not insert batteries in reverse. Observe the polarity markings on battery and equipment
- Do not short-circuit batteries
- Do not charge batteries
- Do not force discharge batteries
- Do not mix batteries
- Do not overheat batteries by exposure to high temperatures and direct sunlight.
- Do not weld or solder directly to batteries
- Do not dismantle batteries
- Do not deform batteries
- Do not dispose of batteries in fire
- A battery with a damaged container should not be exposed to water
- Do not allow children to replace batteries without adult supervision
- Keep batteries out of the reach of children. In case of ingestion of a cell or battery, the person involved should seek medical assistance promptly.
- Equipment intended for use by children should have battery compartments which are tamper-proof
- Do not encapsulate and/or modify batteries
- Exhausted batteries should be immediately removed from equipment and disposed of (see section XIII)
- When discarding batteries with solder tags, insulate the tags by wrapping them with tape, foil, etc.

### Storage:

- Store unused batteries in their original packaging and keep them away from metal objects which may short-circuit them. Storing unpackaged cells together could result in cell shorting and heat build-up.
- Store and display batteries in their original packaging in well ventilated, dry and cool conditions.
- Avoid storing or display batteries in direct sun or in places where they get exposed to rain
- Do not stack battery cartons on top of each other exceeding a specified height. The height is clearly dependent on the strength of the packaging. As for general rule this height should not exceed 1.5 m for cardboard packages or 3 m for wooden cases. The above recommendations are equally valid for storage conditions during prolonged transit. Thus, batteries should be stored away from ship engines and not left for long periods in unventilated metal box cars (containers) during summer.

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## Section VIII - Exposure Controls / Personal Protection

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<u>Respiratory protection (specify type):</u>	Not necessary under conditions of normal use.
<u>Ventilation:</u>	Not necessary under conditions of normal use.
<u>Protective gloves:</u>	Not necessary under conditions of normal use.
<u>Eye protection:</u>	Not necessary under conditions of normal use.
<u>Other protective clothing or equipment:</u>	Not necessary under conditions of normal use.

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## Section IX - Physical and Chemical Properties

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The chemicals mentioned in Section II are contained in a sealed battery can.  
Under conditions of normal use, the chemicals will not be released.

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## Section X - Stability and Reactivity

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Lithium batteries are contained in a stable steel container and are sealed to avoid any chemical release under conditions of normal use.

Conditions to avoid: See Section VII

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## Section XI - Toxicological Information

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### **Swallowing:**

Ingestion of a battery can be harmful. For US call The National Capital Poison Control Center (1-800-222-1222) day or night - for advice and follow-up. For other countries please contact the local Tox Centers.

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## Section XII - Ecological Information

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The chemicals mentioned in Section II are contained in a sealed battery can.  
Under conditions of normal use, the chemicals will not be released.  
It does not pose a physical or health risk to users, see section XIII for disposal.

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## Section XIII - Disposal Considerations

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Waste disposal method:

a) **Be sure to comply with your federal, state and local regulation disposal of used batteries.**

Dispose in accordance with appropriate national and international regulations, below some references.

European Community: according to Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), Annex II, batteries have to be removed from any separately collected WEEE. The removed batteries have to be treated according to the Battery directive 2006/66/EC

US: Lithium batteries are neither specifically listed nor exempted from the Federal Environmental Protection Agency (US EPA) hazardous waste regulations. The only material of possible concern due to its reactivity is lithium metal. However, button cells contain so little lithium that they can be disposed off in the normal municipal waste stream.

**Use a professional disposal firm for disposal of mass quantities of undischarged lithium batteries.**

b) Open cells should be treated as hazardous waste

DO NOT INCINERATE or subject battery cells to temperatures in excess of 212°F (100°C). Such treatment can cause cell rupture.

## Section XIV - Transportation Information

### XIV.I Provisions for the international transportation (pursuant to ICAO-TI/IATA-DGR, IMDG Code, ADR, RID, DOT):

Lithium cells and batteries are subject to:

Area	Method	Organization	Special Provision
International	Air	IATA, ICAO	Packing Instruction 968 - Section II
Europe	Road and Rail	ADR / RID	SP188
International	Marine	IMDG	SP188
U.S.A	Rail, Road, Marine	DOT	DOT 49 CFR Section 173.185

Their regulations are based on the UN Recommendations. Each special provision provides specifications on exceptions and packaging for lithium batteries shipping. All CR batteries of Renata AG meet all special provisions.

Summary of Packing Instruction (IATA Dangerous Goods Regulations 51st Edition):

The minimum requirements necessary to transport as partly regulated goods are as follows:

- 1) For a lithium metal or lithium alloy cell, the lithium content is not more than 1g. For a lithium metal or lithium alloy battery, the aggregate lithium content is not more than 2g.
- 2) Each cell or battery is of the type proven to meet the requirement of each test in the UN Manual of Tests and Criteria, Part III, subsection 38.3.
- 3) Each consignment must be accompanied with a certification that the goods meet the conditions for transportation as "partly regulated" (**Specimen See Annex IV**).
- 4) Each package must be displayed a battery handling label (**Specimen See Annex II**).
- 5) Each package must be capable of withstanding a 1.2 m drop test.

However, if they meet the following requirements of Special Provision 188 of the UN Model Regulations, Packing Instruction 968 IATA/ICAO, Special Provision 310 of the IMDG Code, Special Provision 188 of the ADR and RID (Road and Rail Europe), they are not subject to other provisions of the above mentioned regulations:

- (a) For a lithium metal or lithium alloy cell, the lithium content is not more than 1 g
- (b) For a lithium metal or lithium alloy battery the aggregate lithium content is not more than 2 g
- (c) Each cell or battery is of the type proved to meet the requirements of each test in the *Manual of Tests and Criteria*, Part III, sub-section 38.3;
- (d) Cells and batteries are separated so as to prevent short circuits and are packed in strong packaging, except when installed in equipment; and
- (e) Except when installed in equipment, each package containing more than 24 lithium cells or 12 lithium batteries shall in addition meet the following requirements:
  - (i) Each package shall be marked indicating that it contains lithium batteries and that special procedures should be followed in the event that the package is damaged (**Specimen see Annex II**);
  - (ii) Each shipment shall be accompanied with a document indicating that packages contain lithium batteries and that special procedures should be followed in the event a package is damaged (**Specimen see Annex V**);
  - (iii) Each package is capable of withstanding a 1.2 m drop test in any orientation without damage to cells or batteries contained therein, without shifting of the contents so as to allow battery to battery (or cell to cell) contact and without release of contents; and
  - (iv) Individual packages may not exceed 2.5 kgG and must be labelled with handling label.

(Specimen see Annex II), Overpacks are allowed as per Section II of Packing Instruction 968, and must be labelled with handling label (Specimen see Annex VI)

- (f) All personnel at Renata AG preparing and offering Lithium Batteries received adequate instructions

As used above and elsewhere in these Regulations, "lithium content" means the mass of lithium in the anode of a lithium metal or lithium alloy cell, except in the case of a lithium-ion cell the "equivalent lithium content" in grams is calculated to be 0.3 times the rated capacity in ampere-hours.

**RENATA's lithium cells and batteries do meet the above mentioned provisions.  
They can be described as "Partly Regulated" in the transport documents.**

#### XIV.II Provisions for shipments by air into, out of, or within the U.S. (pursuant to 49 CFR)

In addition to the provisions mentioned under XIV.I for shipments into, out of, or within the US the following provisions of the 49 CFR apply:

Pursuant to Special Provision A 100 of the 49 CFR primary (non-rechargeable) lithium cells and batteries are forbidden for transport on passenger carrying aircraft. To avoid these cells and batteries being loaded on board of passenger carrying aircrafts, packages must be marked pursuant to § 173.185 (b)(5) (Specimen see Annex III), even if the packaging are shipped via highway, rail or vessel. RENATA's primary lithium cells and batteries do meet the provisions of § 173.185 (b).

#### GENERAL HANDLING INSTRUCTIONS

Battery cartons should be handled with care. Rough handling may result in batteries being short circuited or damaged. This may cause leakage, explosion, or fire. (Refer also to Section VII) (Specimen see Annex V)

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#### Section XV - Regulatory Information

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The batteries are in accordance with the directive 2006/66/EC

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#### Section XVI - Other Information

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RENATA's lithium batteries are registered by UNDERWRITERS LABORATORIES INC., NORTHBROOK, IL, U.S.A., under file number MH14002.

Further information is given in RENATA Designer's Guide.

For lithium cells and batteries in general, Safety Standard IEC 60086-4 applies, which also contains detailed recommendations for manufacturers of equipment and users.

For further information on RENATA's lithium cells and batteries visit our web site: [www.renata.com](http://www.renata.com).

ANNEX I

APPROXIMATE WEIGHT CONTENT OF LITHIUM IN RENATA LITHIUM BATTERIES

Model no.	% Lithium Max	Weight of battery (in g)	Qty Li (Max in mg)
CR1025	1.5 %	0.6	9
CR1216	1.1 %	0.7	8
CR1216 MFR	1.3 %	0.7	9
CR1220	1.4 %	0.8	11
CR1220 MFR	1.6 %	0.8	13
CR1225	1.7 %	0.9	15
CR1616	1.3 %	1.1	15
CR1620	1.8 %	1.2	21
CR1632	2.1 %	1.8	38
CR2016	1.4 %	1.7	24
CR2016 MFR	1.5 %	1.7	26
CR2016 alterna	1.1 %	1.8	20
CR2025	2.1 %	2.3	48
CR2025 MFR	2.0 %	2.5	50
CR2025 alterna	2.0 %	2.5	50
CR2032	2.4 %	2.8	67
CR2032 MFR	2.0 %	2.8	56
CR2032 alterna	2.0 %	3.0	60
CR2045	2.2 %	3.7	83
CR2045HT	1.9 %	4.1	79
CR2320	1.6 %	2.7	43
CR2325	1.8 %	3.0	55
CR2430	2.0 %	4.1	80
CR2430 MFR	3.0 %	4.3	129
CR2450HT	2.0 %	6.7	136
CR2450N	2.7 %	5.9	160
CR2477N	3.3 %	8.3	270



## Material Safety Data Sheet

Copyright, 2009, 3M Company. All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

This material safety data sheet (MSDS) is provided as a courtesy in response to a customer request. This product is not regulated under, and a MSDS is not required for this product by the OSHA Hazard Communication Standard (29 CFR 1910.1200) because, when used as recommended or under ordinary conditions, it should not present a health and safety hazard. However, use or processing of the product not in accordance with the product's recommendations or not under ordinary conditions may affect the performance of the product and may present potential health and safety hazards.

### SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

**PRODUCT NAME:** 3M™ Polyethylene Foam Medical Tape 1774W (22mm x 0.56mm) White  
**MANUFACTURER:** 3M  
**DIVISION:** Skin & Wound Care Division  
**ADDRESS:** 3M Center  
 St. Paul, MN 55144-1000

**EMERGENCY PHONE:** 1-800-364-3577 or (651) 737-6501 (24 hours)

**Issue Date:** 06/01/09  
**Supersedes Date:** 01/28/09  
**Document Group:** 23-5544-4

**Product Use:**  
 Intended Use: Medical and retail devices

### SECTION 2: INGREDIENTS

<u>Ingredient</u>	<u>C.A.S. No.</u>	<u>% by Wt</u>
PAPER	None	50 - 60
Foam Backing	Unknown	20 - 30
Acrylic Adhesive	Trade Secret	20 - 30

### SECTION 3: HAZARDS IDENTIFICATION

#### 3.1 EMERGENCY OVERVIEW

**Odor, Color, Grade:** Solid. Polyethylene Foam Tape.  
**General Physical Form:** Solid

**Immediate health, physical, and environmental hazards:** The environmental properties of this product present a low environmental hazard. This product, when used under reasonable conditions and in accordance with the 3M directions for use, should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards.

### 3.2 POTENTIAL HEALTH EFFECTS

**Eye Contact:**

No health effects are expected.

**Skin Contact:**

No health effects are expected.

**Inhalation:**

No health effects are expected.

**Ingestion:**

Physical Blockage: Signs/symptoms may include cramping, abdominal pain, and constipation.

### 3.3 POTENTIAL ENVIRONMENTAL EFFECTS

This substance does not leach metals or other RCRA (Resource Conservation and Recovery Act) listed TCLP (Toxic Characteristic Leaching Procedure) hazardous substances at concentrations that would make the product a hazardous waste.

## SECTION 4: FIRST AID MEASURES

### 4.1 FIRST AID PROCEDURES

The following first aid recommendations are based on an assumption that appropriate personal and industrial hygiene practices are followed.

**Eye Contact:** No need for first aid is anticipated.

**Skin Contact:** No need for first aid is anticipated.

**Inhalation:** No need for first aid is anticipated.

**If Swallowed:** Do not induce vomiting unless instructed to do so by medical personnel. Give victim two glasses of water. Never give anything by mouth to an unconscious person. Get medical attention.

## SECTION 5: FIRE FIGHTING MEASURES

### 5.1 FLAMMABLE PROPERTIES

<b>Autoignition temperature</b>	<i>Not Applicable</i>
<b>Flash Point</b>	<i>Not Applicable</i>
<b>Flammable Limits - LEL</b>	<i>Not Applicable</i>

Flammable Limits - UEL

*Not Applicable*

## 5.2 EXTINGUISHING MEDIA

Use fire extinguishers with class B extinguishing agents (e.g., dry chemical, carbon dioxide).

## 5.3 PROTECTION OF FIRE FIGHTERS

**Special Fire Fighting Procedures:** Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).

**Unusual Fire and Explosion Hazards:** No unusual fire or explosion hazards are anticipated.

**Note:** See STABILITY AND REACTIVITY (SECTION 10) for hazardous combustion and thermal decomposition information.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

**Accidental Release Measures:** Not applicable.

## SECTION 7: HANDLING AND STORAGE

### 7.1 HANDLING

Avoid prolonged or repeated skin contact. This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions.

### 7.2 STORAGE

Not applicable.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 ENGINEERING CONTROLS

Not applicable.

### 8.2 PERSONAL PROTECTIVE EQUIPMENT (PPE)

#### 8.2.1 Eye/Face Protection

Not applicable.

#### 8.2.2 Skin Protection

Avoid prolonged or repeated skin contact.

#### 8.2.3 Respiratory Protection

Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

**8.2.4 Prevention of Swallowing**

Not applicable.

**8.3 EXPOSURE GUIDELINES**

None Established

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

<b>Odor, Color, Grade:</b>	Solid. Polyethylene Foam Tape.
<b>General Physical Form:</b>	Solid
<b>Autoignition temperature</b>	<i>Not Applicable</i>
<b>Flash Point</b>	<i>Not Applicable</i>
<b>Flammable Limits - LEL</b>	<i>Not Applicable</i>
<b>Flammable Limits - UEL</b>	<i>Not Applicable</i>
<b>Boiling point</b>	<i>Not Applicable</i>
<b>Density</b>	<i>Not Applicable</i>
<b>Vapor Density</b>	<i>Not Applicable</i>
<b>Vapor Pressure</b>	<i>Not Applicable</i>
<b>Specific Gravity</b>	<i>Not Applicable</i>
<b>pH</b>	<i>Not Applicable</i>
<b>Melting point</b>	<i>Not Applicable</i>
<b>Solubility in Water</b>	Nil
<b>Evaporation rate</b>	<i>Not Applicable</i>
<b>Percent volatile</b>	<i>Not Applicable</i>
<b>Viscosity</b>	<i>Not Applicable</i>

**SECTION 10: STABILITY AND REACTIVITY**

**Stability:** Stable.

**Materials and Conditions to Avoid:** None known

**Hazardous Polymerization:** Hazardous polymerization will not occur.

**Hazardous Decomposition or By-Products**

<u>Substance</u>	<u>Condition</u>
Carbon monoxide	Oxidation, heat or reaction
Carbon dioxide	Oxidation, heat or reaction

**Hazardous Decomposition:** Under recommended usage conditions, hazardous decomposition products are not expected. Hazardous decomposition products may occur as a result of oxidation, heating, or reaction with another material.

**SECTION 11: TOXICOLOGICAL INFORMATION**

Please contact the address listed on the first page of the MSDS for Toxicological Information on this material and/or its components.

## SECTION 12: ECOLOGICAL INFORMATION

### ECOTOXICOLOGICAL INFORMATION

Not applicable.

### CHEMICAL FATE INFORMATION

Not applicable.

## SECTION 13: DISPOSAL CONSIDERATIONS

**Waste Disposal Method:** Reclaim if feasible. If product can't be reclaimed, dispose of waste product in a sanitary landfill. Alternatively, incinerate the waste product in an industrial, commercial, or municipal incinerator. Dispose of waste product in a sanitary landfill. As a disposal alternative, incinerate in an industrial or commercial facility.

**EPA Hazardous Waste Number (RCRA):** Not regulated

Since regulations vary, consult applicable regulations or authorities before disposal.

## SECTION 14: TRANSPORT INFORMATION

**ID Number(s):**  
70-0001-2638-6

Please contact the emergency numbers listed on the first page of the MSDS for Transportation Information for this material.

## SECTION 15: REGULATORY INFORMATION

### US FEDERAL REGULATIONS

Contact 3M for more information.

### 311/312 Hazard Categories:

Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - No Delayed Hazard - No

### STATE REGULATIONS

Contact 3M for more information.

## CHEMICAL INVENTORIES

This product is an article as defined by TSCA regulations, and is exempt from TSCA Inventory listing requirements.

Contact 3M for more information.

## INTERNATIONAL REGULATIONS

Contact 3M for more information.

This MSDS has been prepared to meet the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200.

## SECTION 16: OTHER INFORMATION

### NFPA Hazard Classification

Health: 0 Flammability: 1 Reactivity: 0 Special Hazards: None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

### Revision Changes:

Section 1: Product name was modified.

Section 1: Division name was modified.

Page Heading: Product name was modified.

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**Technical Information Sheet**  
**Product Number 1774W**  
**3M™ White Polyethylene Foam Single Coated Medical Tape**

Effective: February 2007  
Supersedes all previous specifications

**Features and Benefits:**

- Hypoallergenic Pressure Sensitive Adhesive
- Conformable Cushioning
- Easy to Apply
- ETO & Gamma Compatible
- Good Adhesion to Skin
- Opaque White

**Composition:**

<b>Tape Caliper</b>	22 mils (0.6 mm) Polyethylene Foam Tape
<b>Backing</b>	20 mils (0.5 mm) White Closed-cell Polyethylene Foam
<b>Adhesive</b>	Acrylate, designed for medical/surgical applications
<b>Release Liner</b>	63 lb. Poly-coated Kraft paper, silicone on one side (4.6 mil/0.12 mm)

**Typical Properties<sup>+</sup>:**

<b>Adhesion to Steel, 180° Peel</b>	24 ounces/inch width (6.7 N/25mm width) (680gm/25mm width)
<b>Liner Release</b>	31 gm/inch width (31 gm/25 mm width)

<sup>+</sup>3M test methods are available upon request.

**Roll Description:** Tape supplied on 3 inch (76 mm) diameter cores.

<b>Length, Maximum</b>	210 yards (192 m) ± 2%
<b>Width, Maximum</b>	48 inch (122 cm) ± 1/16 in (1.5 mm)

**Splices:** Splices on the tape are intended for continuous processing.

<b>Roll Width</b>	<b>Maximum Number of Splices per Roll</b>
≤ 8 inch (20 cm)	3 per 125 yd (113 m)
	4 per 175 yd (158 m)

Information on the splice frequency in roll widths greater than 8 inch (20 cm) is available upon request.

**Packaging and Recommended Storage:**

Product as supplied in original packaging will maintain stated properties for a period of two years from date stamped on shipping container when stored at temperatures between 50-80°F (10-27°C) and a relative humidity between 40-60 percent.

**Please see reverse side for important product, safety and warranty information.**

**Product and Safety Information:** User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M will provide Material Safety Data Sheets and results of toxicity testing upon request. In every case before using any product in full scale production users should conduct their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

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Call us at Customer Service to place an order: 800-742-1994 (U.S.). Visit our website: [www.3M.com/medicalspecially](http://www.3M.com/medicalspecially) for product and services information, news about conferences we will be attending, new product highlights or to make a direct inquiry.

To have a sales representative contact you, to request samples or clinical and safety summaries, please contact us at 3M HELPLINE 800-228-3957 (U.S.) or for international inquiries, please contact your local country representative. Our 3M Medical Specialties subsidiary contacts are listed below.

## International Locations

### Argentina

3M Argentina S.A.C.I.F.I.A.  
Tel.: 54-11-4339-2400  
Fax: 54-11-4339-2640

### Dominican Republic

3M Dominicana  
Tel: (809) 530-6560 X499  
Fax: (809) 530-2960

### Kazakhstan

3M Representation Office  
Tel: +7 3272 509 944  
Fax: +7 3272 509 573

### Poland

3M Poland Sp.z o.o.  
Tel: (48 22) 739 60 00  
Fax: (48 22) 739 60 01

### Thailand

3M Thailand Ltd.  
Tel: (66)2 260 8577 Ext.175  
Fax: (66)2 261 7535

### Australia

3M Health Care  
Tel: 1 300 363 878  
Fax: 1 800 060 888

### Finland

Suomen 3M Oy  
Tel.: 358-9-52-521  
Fax: 358-9-512-29-44

### Korea

3M Korea Ltd.  
Tel: 82-2-3771-4286  
Fax: 82-2-786-2825

### Portugal

3M Portugal  
Tel: 351-21-3134500  
Fax: 351-21-3134680

### Taiwan

3M Taiwan Ltd.  
Tel: 886-2-2704-9011  
Fax: 886-2-2706-0355

### Belgium

3M Belgium N.V./S.A.  
Tel: 32-2-722-5111  
Fax: 32-2-720-0225

### France

Laboratoires 3M Santé  
Tel: 33-1-3031-8376  
Fax: 33-1-3031-8378

### Malaysia

3M Malaysia Sdn. Bhd.  
Tel: 6-03-7806 2888  
Fax: 6-03-7806 2902

### Russia

3M Russia  
Tel: 7 (495) 784-74-74  
Fax: 7 (495) 784-74-75

### Turkey

3M Turkey  
Tel: 9 (0212) 3507777  
Fax: 9 (0212) 2821742

### Brazil

3M DO Brasil Ltda.  
Tel: 55-19-864-7171  
Fax: 55-19-864-7848

### Germany

3M Medica  
Tel: 49 2131 14 40 00  
Fax: 49 2131 14 49 99

### Mexico

3M México, S.A. de C.V.  
Tel: +52-55-5270-0400  
Fax: +52-55-5270-0433

### Singapore

3M Technologies (S) Pte. Ltd.  
Tel: 65-6450-8866  
Fax: 65-6455-2130

### Ukraine

3M Ukraine  
Tel: +380 44 490 57 77  
Fax: +380 44 490 57 75

### Canada

3M Canada  
Tel: 800 364-3577  
Fax: 800 341-4630

### Hong Kong

3M Hong Kong Ltd.  
Tel: (852) 2806 6111  
Fax: (852) 2234 6044

### Middle East

3M Gulf Ltd.  
Tel: 971-4-3670-777  
Fax: 971-4-3670-699

### Sri Lanka

3M Lanka (Pvt.) Ltd.  
Tel: (94) 11 2785701  
Fax: (94) 11 4410083-4

### United Kingdom & Ireland

3M Health Care Ltd.  
Tel: 44-1509-611-611  
Fax: 44-1509-237-288

### Chile

3M Chile S.A.  
Tel: (56-2) 4103000  
Fax: (56-2) 4103400

### Hungary

3M Hungária Kft.  
Tel: (36-1) 270-7777  
Fax: (36-1) 320-0951

### The Netherlands

3M Nederland B.V.  
Tel: 31-715-450-450  
Fax: 31-715-450-212

### Spain

3M España, S.A.  
Tel: 34-91-321-6000  
Fax: 34-91-321-6002

### Venezuela

3M Manufacturera Venezuela  
Tel: 58-241-8391911  
Fax: 58-241-8391928

### China

3M China Ltd.  
Tel: 86-21-6275-3535  
Fax: 86-21-5208-2205

### India

3M India Ltd.  
Tel: 0091-80-2223 1414  
Fax: 0091-80-22231450

### New Zealand

3M New Zealand  
Tel: 64-9-444 4760  
Fax: 64-9-443 7885

### Sweden

3M Svenska AB  
Tel: +46-8-92 21 00  
Fax: +46-8-92 24 22

### Viet Nam

3M Viet Nam Ltd.  
Tel: 84 8 640986  
Fax: 84 8 641024

### Colombia

3M Colombia S.A.  
Tel: 57-1 4108585  
Fax: 57-1 4161677

### Indonesia

PT 3M Indonesia  
Tel: (62-21) 520 3401  
Fax: (62-21) 520 3106

### Peru

3M Peru S.A.  
Tel: 511-224-2728  
Fax: 511-224-3171

### Switzerland & Eastern Europe

3M (Schweiz) AG  
Tel: +41 44 724 92 44  
Fax: +41 44 724 94 80

### Czech Republic

3M Cesko s.r.o.  
Tel: +420-261 380 111  
Fax: +420-261 380 110

### Italy

3M Italia SPA  
Tel: +39 2 7035-2406  
Fax: +39 2 7035-2484

### Philippines

3M Philippines  
Tel: (632) 8133781 to 95  
Fax: (632) 8145873 to 74

### Denmark

3M a/s  
Tel: 45-43-48-0100  
Fax: 45-43-96-8596

### Japan

3M Health Care Ltd.  
Tel: 81-3-3709-8289  
Fax: 81-3-3709-8754



**3M Medical Specialties**  
3M Center, Building 275-5W-05  
St. Paul, MN 55144-1000 USA  
Tel.: 800 228-3957



# MATERIAL SAFETY DATA SHEET

## **1. Substance/Product identification**

<b>Product name:</b>	<b>HYDROGEL Electrodes and Cosmetics</b>
<b>Company:</b>	First Water Limited Hilldrop Lane Ramsbury Marlborough Wiltshire, SN8 2RB
<b>E-mail contact</b>	info@first-water.com
<b>Preparation/Revision date</b>	06 March 2012
<b>Product type</b>	Multipurpose
<b>Emergency telephone number:</b>	+ 44 (0) 1672 522 133
<b>MSDS No</b>	Electrodes and Cosmetics v5-06032012

## **2. Hazard identification**

2.1 Classification of the substance or mixture EC No 1272/2008.

This product does not meet the classification requirements of the current European legislation 67/548/EC or 1999/45/EC

<b>Main Hazards:</b>	Not classified as hazardous.
<b>Routes of Entry:</b>	Eye contact – ingestion – skin contact.
<b>Carcinogenic Status:</b>	Not considered carcinogenic by NTP, IARC and OSHA.
<b>Health Effects – Eyes:</b>	Do not contact this product with eyes.
<b>Health Effects – Skin:</b>	This product is intended for skin contact.
<b>Health Effects – Ingestion:</b>	This product is not considered toxic, but as with any material, may be harmful if ingested in large quantities.

## **3. Composition/information on ingredients**

### Chemical characterisation

<b>Gel:</b>	HYDROGELS Electrodes and Cosmetics
<b>Product name:</b>	N/A
<b>CAS number:</b>	N/A
<b>EEC number:</b>	N/A

## **4. First Aid measures**

**Eye contact:** Irrigate thoroughly with water for 5 minutes, holding the eye open. If discomfort persists, obtain medical attention.

**Skin contact:** Wash skin thoroughly with soap and water.

#### **5. Fire fighting measures**

**Flash point:** N/A

**Upper flammable limit:** Not determined

**Lower flammable limit:** Not determined

**Suitable extinguishing media:** Water spray  
Foam  
Dry powder  
Carbon Dioxide

**Unusual fire & explosion hazards:** Material will not burn until water has been evaporated. Toxic fumes, gases or vapours may evolve on burning.

**Auto-ignition point:** Not determined

**Explosion data:** Material does not have explosive properties.

#### **6. Accidental release measures**

Not applicable. No specific measures necessary.  
Carefully sweep up and dispose of in accordance with local regulations.

#### **7. Handling and storage**

**Handling procedures:** Keep in sealed pouch as supplied when not in use.

**Storage:** Store at 5-35 C (and preferably at room temperature-15° to 25°C recommended)  
Keep sealed in supplied packaging and protect from direct sunlight and moisture until ready for use. Reseal in original bags any unused material.

**Conversion:** Convert in a well ventilated area at 15-25C and after conditioning at this temperature for at least 24 hours in original packaging (ex drum).

#### **8. Exposure controls/personal protection**

As appropriate to quantity handled.

**Respirator:** N/A

**Ventilation:** N/A

<b>Gloves:</b>	Chemically resistant
<b>Eye protection:</b>	Wear safety glasses
<b>UK exposure limits:</b>	None assigned.

## 9. Physical and chemical properties

<b>Form:</b>	Hydrogel and plastic/paper covers.
<b>Vapour pressure (mm Hg):</b>	Not determined
<b>Specific gravity:</b>	Not determined
<b>Water solubility:</b>	Swellable/absorbent
<b>Percent volatile:</b>	Not determined
<b>Vapour density:</b>	N/A
<b>Evaporation rate:</b>	Not determined
<b>Odour:</b>	Mild
<b>Viscosity:</b>	N/A
<b>Odour threshold:</b>	Unknown
<b>Boiling point:</b>	N/A
<b>Freezing point:</b>	Hydrogels do not freeze except at exceptionally low temperatures. Temperatures below -5C should be avoided.
<b>Molecular weight:</b>	N/A (cross-linked polymer)

## 10. Stability and reactivity

<b>Stability:</b>	Material is normally stable at moderately elevated temperatures and pressures.
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## 11. Toxicological information

Hydrogels products (or substantially equivalent material) has been tested according to:

**International Standard ISO 10993-10(1995)** – Biological Evaluation of Medical Devices, Part 10: Acute (Single Exposure) Skin Irritation Testing of the Gel.

**International Standard ISO 10993-10(1995)** – Biological Evaluation of Medical Devices, Part 10: Maximisation Sensitisation Test.

**International Standard ISO 10993-5** – Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity, Extract Method.

No evidence of carcinogenic properties. No evidence of mutagenic or teratogenic effects.

Principle hydrogel component is approved for Use as a Food Contact material by the FDA.

## 12. Ecological information

No environmental hazard is anticipated provided that the material is handled and disposed of with due care and attention.

## 13. Disposal considerations

Chemical residues are generally classified as special waste and as such are covered by regulations which vary according to location. Contact your local waste disposal authority for advice or pass to a chemical disposal company.

## 14. Transport information

Not regulated.

**UN number:** N/A  
**IMDG:** N/A  
**ICAO:** N/A  
**ADR/RID Hazard:** N/A

## 15. Regulatory information

**Symbol(s):** N/A  
**Indication of danger:** N/A  
**Precautionary labels:** This material has no known hazards as defined by local laws.  
**EEC number:** N/A

## 16. Other information

HMIS Codes Health 0, Fire 0, Reactivity 0.

Relevant R phrases Not applicable

Revision Indicators

Section	Changed
1 Substance /Product Identification	4 April 2009
2 Hazard Identification	6 March 2012
3 Composition/Information on Ingredients	4 April 2009
7 Handling and Storage	6 March 2012
8 Exposure Controls/Personal Protection	4 April 2009
11 Toxicological Information	6 March 2012
16 Other Information	4 April 2009

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