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SPECIFICATION

PSDS RENASYS EDGE Device

Approvals

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Signature Date/Time:	05 NOV 2024 11:25 UTC
Global Date/Time:	05 NOV 2024 11:25 UTC
Representation:	Author Signature
Signature Reason:	Document Management: Status Change
Signatory Name:	David Adebola
Signature Date/Time:	22 NOV 2024 10:45 UTC
Global Date/Time:	22 NOV 2024 10:45 UTC
Representation:	Engineering Signature
Signature Reason:	Document Management: Status Change

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Product Safety Data Sheet

1a) PRODUCT NAME(S):

RENASYS™ EDGE – Negative Pressure Wound Therapy (NPWT) 66803126

RENASYS™ EDGE Battery Pack 4 Cell – 66803180

1b) INTENDED USE(S):

RENASYS™ EDGE NPWT is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it may promote wound healing via removal of fluids, including irrigation and body fluids, wound exudates and infectious materials.

Appropriate wound types include: Chronic, Acute, Traumatic, Sub-acute and dehisced wounds, Ulcers (such as pressure or diabetic), Partial thickness burns, Flaps and Grafts

1c) Details of Supplier of the Product Safety Data Sheet:

Smith & Nephew Medical

101 Hessle Road

Hull

HU3 2BN

Telephone: 01482 225181 (24 hours)

Email: QACompliance.Hull@smith-nephew.com

2. HAZARD INFORMATION:

2.1 Classification of the substance or mixture:

The device is considered to cause no adverse effects on health or the environment during normal handling and use. The product contains a Lithium-Ion battery that if compromised the contents are classified as Hazardous – See transport Information.

2.2 Label Elements:

See Transport Information, Section 14

2.3 Other Hazards

Contains a Lithium-Ion battery.

3. COMPOSITION / INFORMATION ON INGREDIENTS:

The RENASYS™ EDGE NPWT system is comprised of the device, canisters (300ml available with and without solidifier or 800ml with solidifier), clamp, carry bag and carry strap. RENASYS EDGE is compatible with various RENASYS Foam and Gauze Wound dressing kits. This PSDS is intended for the Pump device and Battery only.

RENASYS™ EDGE NPWT Pump Device: The device includes a vacuum pump, printed circuit boards, LCD display, electrical wiring, a Lithium-Ion Battery, silicone tubing, silicone check valve and silicone solenoid valve. All of the above are housed or attached to the outer case which is manufactured from Chi Mei PA-765B (acrylonitrile butadiene styrene), a flame retardant material, and fastened together by steel screws.

4. FIRST AID:

4.1 First Aid General Information

Not Applicable

4.2 Most important symptoms and effects, both acute and delayed:

Not Applicable

4.3 Indication of any immediate medical attention and special treatment needed:

Not Applicable

a) Inhalation	Not Applicable
b) Contact with skin	Not Applicable
c) Contact with eyes	Not Applicable
d) Ingestion	Not Applicable

5. FIRE AND EMERGENCY MEASURES:

5.1 Extinguishing media

Suitable extinguishing media:

A dry chemical and carbon dioxide is required for extinguishing due to the Lithium-Ion batteries.

Unsuitable extinguishing media:

Water should not be used if installed into the mains electricity.

5.2 Special hazards arising from substance or mixture

If ignited toxic fumes may be expelled including ammonia, aromatic and aliphatic hydrocarbon fractions, carbon monoxide, carbon dioxide, and hydrogen cyanide. Therefore, appropriate self-contained breathing apparatus should be worn when fighting a fire. Keep all personnel away from the fire.

5.3 Advice for firefighters

Protect skin from contact.

If fire is in a confined space, self-contained breathing apparatus should be worn.

6. ACCIDENTAL RELEASE MEASURES:

6.1 Personal precautions, protective equipment and emergency procedures (for non-emergency and emergency personnel)

Not Applicable

6.2 Environmental precautions

Not Applicable

6.3 Methods and material for containment and cleaning up

Not Applicable, manual clean-up will apply.

6.4 Reference to other sections

Not Applicable

7. HANDLING AND STORAGE PRECAUTIONS:

7.1 Precautions for safe handling

- Do not puncture, crush, incinerate or expose the battery to temperatures exceeding 100°C.
- Avoid using around flames or ignition.
- Use only the AC power cord provided with the device.

7.2 Conditions for safe storage, including any incompatibilities

- Store in a dry place out of direct light. Short term storage and transport temperature should

be -25 to 70°C (-13 to 158°F) and long term storage should be 5 to 40°C (41 to 104°F). If the device has been stored at temperatures below freezing, it must be brought to room temperature prior to use or the device may be damaged.
- Do not puncture, crush, incinerate or expose the battery to temperatures exceeding 100oC. Avoid using around flames or ignition. Use only AC power cord provided with the device.

7.3 Specific End Use

See Section 1b

8. EXPOSURE CONTROLS/PERSONAL PROTECTION:

8.1 Control Parameters

Not Applicable

8.2 Exposure Controls

Not Applicable

8.3 Personal Protective Equipment

Not Applicable

9. PHYSICAL AND CHEMICAL PROPERTIES:

9.1 Information on basic physical and chemical properties

See Product Description.

10. STABILITY AND REACTIVITY:

10.1 Reactivity

Product is stable and non-reactive.

10.2 Chemical Stability

Product is stable and non-reactive.

10.3 Possibility of Hazardous Reactions

Product is stable and non-reactive.

10.4 Conditions to Avoid

Product should be stored in a dry place, at a temperature between 5 to 40°C and out of direct sunlight.

10.5 Incompatible Materials

Not Applicable

10.6 Hazardous Decomposition Products

Product is stable and non-reactive.

11. TOXICOLOGICAL INFORMATION:

11.1 Information on Toxicological Effects

Not Applicable

12. ECOLOGICAL INFORMATION:

12.1 Toxicity

Not Known

12.2 Persistence and Degradability

Not Known

12.3 Bio accumulative potential

Not Known

12.4 Mobility in soil

Not Known

12.5 Results of PBT and vPvB assessment

Not Known

12.6 Other Adverse Effects

Not Known

13. DISPOSAL CONSIDERATIONS:

13.1 Waste Treatment Methods

Dispose of in accordance with local/ national environmental waste guidelines for electrical medical devices containing Lithium-Ion battery. In European countries this product should be separated and sent to a designated collection point for recycling of Waste Electrical and Electronic Equipment (WEEE).

Disposal of battery: follow local guidelines and battery label for proper disposal. Do not

puncture, crush, incinerate or expose the battery to temperature exceeding 100°C. Improper disposal of Lithium-Ion battery may result in fire explosion and burns.

14. TRANSPORT INFORMATION:

14.1 UN Number

RENASYS™ EDGE - 66803126

3481

RENASYS™ EDGE Battery Pack 4 Cell – 66803180

3480

14.2 UN Proper Shipping Name

RENASYS™ EDGE - 66803126

Lithium-Ion Batteries Contained in Equipment

RENASYS™ EDGE Battery Pack 4 Cell – 66803180

Lithium-Ion Batteries

14.3 Transport Hazard Classes

Classification 9

The lithium battery in the RENASYS EDGE is not restricted and meets the following listed below, and is properly packaged and is classed as a battery installed in equipment / lithium-ion battery:

1. For batteries, the Watt Hour rating is not more than 100 Wh.
2. Each battery has been successfully tested and complies with the UN Manual of Test and Criteria, Part III, subsection 38.3
3. Each battery has been manufactured under a quality management program as specified in 2.9.4 of the UN Model Regulations.

These products meet the requirements for transportation under:

- UN Model Regulations Special Provisions 188 and 230
- International Civil Aviation Organization (ICAO) Technical Instructions and the
- International Air Transport Association (IATA) Dangerous Goods Regulations Packing Instruction:
  - 967 Section II (UN3481, Lithium-Ion Batteries Contained in Equipment)
  - 965 Section IB (UN3480, Lithium-Ion Batteries)
- International Maritime Organization (IMO) Special Provisions 188 and 230
- European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) Special Provisions 188 and 230
- U.S. Department of Transportation (DOT) 49 CFR 173.185 and 173.185(c)
- Canadian Transport of Dangerous Goods Regulations (TDGR) Special Provision 34

RENASYS™ EDGE - 66803126

Batteries when installed in equipment shall be protected from damage and short circuit, and the equipment shall be equipped with an effective means of preventing accidental activation. When batteries are installed in the equipment, the batteries shall be packed in strong outer packaging constructed of suitable material of adequate strength and design in relation to the packaging's capacity and its intended use.

RENASYS™ EDGE Battery Pack 4 Cell – 66803180

Each battery must be packed in inner packaging that completely enclose the battery.

Each battery must be protected so as to prevent short circuits (including protection against contact with conductive materials within the same packaging that could lead to a short circuit).

Each inner package must be packed in a strong outer packaging.

Each package must be capable of withstanding a 1.2 m drop test in any orientation without:

• damage to cells or batteries contained therein

• shifting of the contents so as to allow battery to battery (or cell to cell) contact

• release of contents

Maximum gross weight per package: 30.0 kg Gross

All lithium-ion cells and batteries shipped by themselves (UN 3480) are forbidden for transport as cargo on passenger aircraft. All packages prepared in accordance with Packing Instruction 965, Section IB, must bear a Cargo Aircraft Only label, in addition to other required marks and/or labels.

All lithium ion cells and batteries (UN 3480 only) must be shipped at a state of charge (SoC) not exceeding 30% of their rated capacity.

UN 3480, lithium-ion batteries prepared in accordance with Section IB of PI 965 must not be packed in the same outer packaging with dangerous goods classified in Class 1 (explosives) other than Division 1.4S, Division 2.1 (flammable gases), Class 3 (flammable liquids), Division 4.1 (flammable solids) or Division 5.1 (oxidizers). Packages containing cells or batteries must not be placed in an overpack with packages containing dangerous goods classified in Class 1

other than Division 1.4S, Division 2.1, Class 3, Division 4.1 or Division 5.1.

14.4 Packaging Group

Not Applicable

14.5 Environmental Hazards

Not Applicable

14.6 Special Precautions for the user

Packages should be handled with care. Rough handling may result in batteries being short circuited or damaged. This may cause leakage, explosion, or fire.

DAMAGED LITHIUM BATTERIES ARE FORBIDDEN FOR TRANSPORT IN ANY MODE

15. REGULATORY INFORMATION:

15.1 Safety, Health and Environmental Regulations / Legislation specific to the substance or mixture

EU Legislation:

Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Safety Data Sheet requirements of Regulation EC no 1272/2008'

Guidance:

ECHA Guidance on the compilation of safety data sheets (Version 2.1: February 2014)

15.2 Chemical Safety Assessment

Not Applicable

16. ADDITIONAL INFORMATION:

Full text of H statements referred to in other sections

Full text of P statements referred to in other sections

Test Summary of Lithium-Ion Battery (UN38.3)

T1	Altitude	Pass
T2	Thermal	Pass
T3	Vibration	Pass
T4	Shock	Pass
T5	External Short Circuit	Pass
T6	Impact / Crush	N/A (Cell Level)
T7	Overcharge	Pass
T8	Forced Discharge	N/A (Cell Level)

17a) REFERENCE NUMBER	2015899
17b) DATE OF ISSUE	5th November 2024

This information is provided in accordance with the requirements of the UK Health and Safety at Work Act 1974, and specifically in order to assist users of the product to make their 'assessment of health risks' as required by the UK Control of Substances Hazardous to Health Regulation 2002 (COSHH assessments). Provision of this information does not preclude users from seeking advice from other sources as indicated in the COSHH guides. The information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patient.

REASON FOR CHANGE

Document Version	Section/Paragraph Changed	Change Made	Date
01	Whole Document	Initial release as part of CCA 6043	9th March 2023
02	Section 1a Section 3	Addition of RENASYS EDGE Battery Pack 4 Cell (SKU 66803180) as part of CCA 6470	5th November 2024

Plant Number(s):

None

Product Code(s):

66803126

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