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SPECIFICATION
RENASYS EDGE Device
REF 66803126

Approvals

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SPECIFICATION

RENASYS EDGE Device

REF 66803126

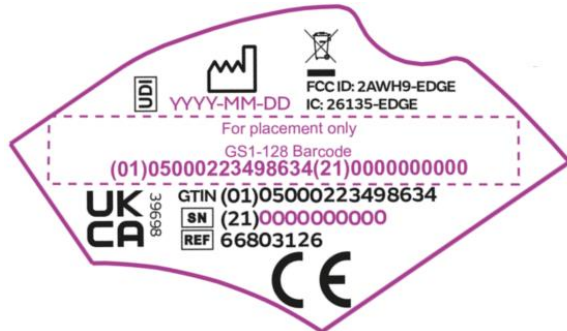
Packaging & Labelling Specification

UNIT

Device

Product Bottom Barcode Label

S&N Artwork ref: 39698



The labeling shall contain the following variable information for identification and traceability:

1. Manufacture date with format  YYYY-MM-DD
2. Serial number to provide traceability to the device. And it is unique and assigned per manufacturer specifications.

1	2	3	4	5	6	7	8	9	10
Product Mfg. Location	Product Identifier	Product Rev	Month	Year		Numerical Build Sequence			
P	E	A-Z	A-L	0 to 9	0 to 9	0 to 9	0 to 9	0 to 9	0 to 9

These fields are described as follows:

- Mfg. Location = P (Plexus Kelso)
- Product Ident. = E (RENASYS EDGE)
- Product Revision = A for initial launch
- Month codes: A = January to L = December
- Year = two digits for manufacturing year e.g. 2025 = '25'
- Numerical Build sequence starts at '0001' at the beginning of each month

e.g.  (21)PEAA250001

3. A GS1-128 barcode containing a fixed 14-digit product GTIN (A GTIN assigned by Smith+Nephew), and serial number in the formats below:
e.g. (01)05000223498634(21)PEAA250001

Note: Human Readable barcode information to be located directly below the GS1-128 barcode with addition of Application Identifier (AI) references (01) for GTIN (21) for serial number.

Note: The barcode printing quality should comply with GS1 requirement, the barcode grade scan result must result in over all grade of 'A' or 'B' , no less than 'C'.

Note: All the purple text on artworks image are just for reference or placeholder, they will be replaced by the actual information when manufactured.

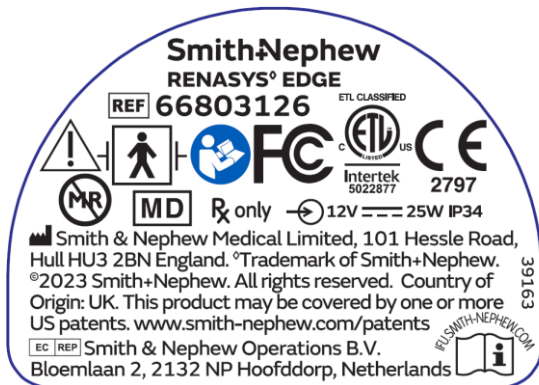
Note: For any artwork change, please check the label in Service & Repair Packaging, Labelling And Software Specification (PLSS) - WI-314753 to make sure they are all the latest.

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Product Rear Badge Label

S&N Artwork ref: 39163



Primary Packaging

One device placed top first into clear plastic bag, bag folded over device and sealed with tape.

Secondary Packaging

One bagged device per Shipper Case.

Shipper Case construction details

1. Make up OUTSIDE BOX, and seal base with Packing Tape.
2. Insert the FOAM into OUTSIDE BOX.
3. Place RENASYS EDGE device (in bag) upright into FOAM as shown.



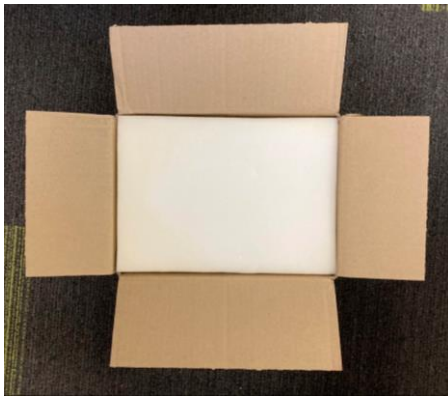
4. Place a cardboard on the foam as shown.



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5. Place a foam pad on the cardboard as shown.



6. Apply Packing TAPE, on top side of OUTSIDE BOX.
7. Apply a UN3481 label (Plexus part number 1588171-410) to OUTSIDE BOX as the device contains a lithium battery.

Artwork Image for reference only:



8. Apply CASE LABEL to SHIPPER CASE. 1" x 1" from the top right edge of the long side of SHIPPER CASE.

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Case Label

S&N Artwork ref: 39715

RENASYS[®] EDGE		REF 66803126	1 _{x1}	Smith+Nephew
Negative Pressure Wound Therapy		BG Терапия на рани с отрицательно налягане	SI Zdravljenje ran z negativnim tlakom	 Smith & Nephew Medical Limited, 101 Hessle Road, Hull HU3 2BN England. *Trade Mark of / Marque de commerce de Smith+Nephew. Country of Origin: UK / Pays d'origine: Royaume-Uni. www.smith-nephew.com EC REP Smith & Nephew Operations B.V., Bloemlaan 2, 2132 NP Hoofddorp, Netherlands
FR Traitement des plaies par pression négative	CZ Podtlaková léčba ran	TR Negatif Basıncılı Yara Tedavisi	AR علاج الجروح بالضغط السلبي	
DE Unterdruck-Wundtherapie	HR Terapija rane negativnim tlakom	CN 負壓傷口治療	KO 음압 상처 치료	
ES Tratamiento de heridas por presión negativa	EE Negatiivse rõhuga haavaravi (vaakumravi)	MY Terapi Luka Tekanan Negatif	RU отрицательным давлением	
PT Terapia de feridas por pressão negativa	GR Θεραπεία τραύματος με αρνητική πίεση	TH การรักษาบาดแผลด้วยแรงลบ	VN Trị liệu vết thương áp lực âm	
IT Terapia a pressione negativa	HU Negatív nyomásos sebkezeléshez			
NL Negatieve druktherapie	LV Negatīva spiediena brūču terapija			
DK Sårbehandling med negativt tryk	LT Neigiamo slėgio žaizdų Terapija			
NO Sårbehandling med negativt trykk	PL Podciśnieniowe leczenie ran			
FI Haavan alipaineimuhoito	RO Terapie cu presiune negativă a plăgii			
SE Sårbehandlingssystem med undertryck	SK Liečba rany podtlakom			

 2797									 總務省指定 第AC-24066号	 TA-2024/0195
 For placement only GS1-128 Barcode (01)05000223498634(21)000000000										 KC ID: R-R-93S-EDGE-66803126
										39715

Label affixed to the case side printed with:

1. The serial number, manufacture date as well as the GTIN are the same format as Product Bottom Barcode Label.
2. A GS1-128 barcode containing a fixed 14-digit product GTIN (A GTIN assigned by Smith+Nephew), serial number in the formats below:
e.g. (01)05000223498634(21)PEAA250001

Note: The serial number, manufacture date and GTIN should be as same as Product Bottom Barcode Label.

Note: Human Readable barcode information to be located directly below the GS1-128 barcode with addition of Application Identifier (AI) references (01) for GTIN (21) for serial number.

Note: The barcode printing quality should comply with GS1 requirement, the barcode grade scan result must result in over all grade of 'A' or 'B', no less than 'C'.

Note: All the purple text on artworks image are just for reference or placeholder, they will be replaced by the actual information when manufactured.

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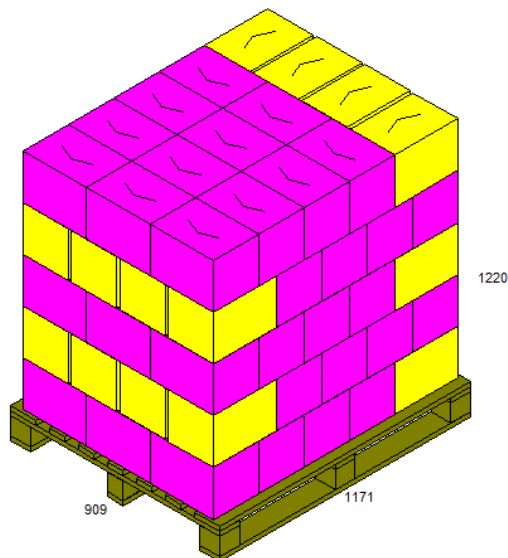
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PALLETISATION

80 Shipper cases (80 units) in 5 layers of 16 are stacked onto a 1200mm x 1000mm UK pallet.
All labels on cases at the outer edges must face outwards and be the right way up.
The load shall be secured to the pallet by means of stretch wrap film, so that the pallet and load are wrapped as a complete unit.

Cases per Pallet	80
Layers per Pallet	5
Cases per Layer	16
Units per Pallet	80



Do Not Stack sample

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Palletisation Requirements

1. Pallets that are to be transported across international borders must be constructed of heat-treated wood, plastic, or be otherwise IPPC/ISPM15 compliant.
2. Pallet specification must comply with the recipient's market standard, i.e. British 4-way entry in the UK, Euro in mainland Europe, and US standard in America. Additional information will be supplied by S&N as needed.
3. Only one product code may be stacked on the same pallet. Multiple lots of the same product code on the same pallet are permitted if clearly segregated by layer and/or physical barrier and additional identification is present to highlight each mixed pallet. Serialized items may be stacked on the same pallet without segregation.
4. Only product from one purchase order may be stacked on the same pallet.
5. A pallet slip sheet (barrier between the product and the pallet) must be used to protect the bottom layer of product from dirt, dust, and moisture, as well as to keep the Shipper Boxes from becoming wedged among the pallet slats.
6. Product must not overhang the edge of the pallet.
7. Product Shipper Box labels must face outward wherever possible.
8. Corner boards must be used to protect the edges of the completed pallet.
9. Pallet top sheets must be used to protect the product from dirt, dust and moisture.
10. Product must be secured to the pallet by the use of stretch film or shrink wrap using proper tension. If necessary, non-metal banding may be used to further secure the product to the pallet.
11. Pallets must be of sound quality - having no broken boards, protruding nails, etc. (wooden), and having no cracks or significant damage (plastic).
12. A "Do Not Stack" cone fixed to the top.

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REASON FOR CHANGE

Document Version	Section/Paragraph Changed	Change Made	Date
1	New	First Issue as per CCA6043	15-Nov-2022
2	Rework to PLS template Product Bottom Barcode Label Product Rear Badge Label Case Label	Update the PLS template to align with AWD PLS template FRM-410974 v1 Below update was done as per CCA 6474 version 2 Update S&N Artwork Ref from 36265 to 39698, update artwork image accordingly. Update S&N Artwork Ref from 36264 to 39163, update artwork image accordingly. Update S&N Artwork Ref from 36266 to 39699, update artwork image accordingly.	23 rd Feb 2024
3	Product Bottom Barcode Label Case label	As per NC 58939 Add the serial number format table and description. Update the serial number sample to reflect the format. Update the serial number sample to align with what in the bottom barcode label.	19 th September 2024
4		There is no content change/update to PLS main document, just corrected a date typo identified in supplier approval letter.	30 th September 2024
5	Case label Product Bottom Barcode Label & Case label All	As per CCA6827 Update S&N Artwork Ref from 39699 to 39715, update artwork image accordingly. Add one note to highlight any change to the labels, PLSS should be checked to make sure the labels used in S&R OKC are the latest. Update date in sample to latest	7 th May 2025

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Plant Number(s):

None

Product Code(s):

66803126

*** END OF DOCUMENT ***