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LISTE DE DIFFUSION

INTERNE	<i>Services concernés</i>	
	Achats	<input type="checkbox"/>
	Affaires Réglementaires	<input type="checkbox"/>
	Assurance Qualité	<input checked="" type="checkbox"/>
	Atelier bonding	<input type="checkbox"/>
	Atelier hybride	<input type="checkbox"/>
	Clinique	<input type="checkbox"/>
	Conditionnement	<input type="checkbox"/>
	Contrôle entrée électrique	<input checked="" type="checkbox"/>
	Contrôle entrée mécanique	<input type="checkbox"/>
	Contrôle entrée puce	<input type="checkbox"/>
	Finition	<input type="checkbox"/>
	Intégration	<input type="checkbox"/>
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<i>SOCIETES EXTERNES</i>	
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SELCO	<input type="checkbox"/>
STAE	<input type="checkbox"/>
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1. INTENDED USE

This specification describes a miniature coil for implantable telemetric devices.

2. IDENTIFICATION

- Customer part number : **SC0T421D**
- Manufacturers and specific technical specification reference : Z08-31-CHI

MANUFACTURER	SPECIFICATION ADD-ON
Intricon Tibbetts corp.	1SC0T421 +last revision

3. RAW MATERIALS REQUIREMENTS

The requirements in this section apply to magnet wire used in these coils.

3.1. WIRE PURCHASE SPECIFICATION

Supplier shall establish and maintain a written purchase specification. This document shall specify :

- Wire size
- Overall-diameter range
- Insulation
- Enameling machine
- Wire lubrication
- Test Certificate for Magnet Wire, Level 1 with EAPC
- Test data for Lubrication (with manufacturing limits)

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3.2. WIRE CERTIFICATE OF CONFORMANCE

Supplier shall require a Test Certificate for Magnet Wire, Level 1 with EAPC from wire manufacturer for each wire lot, containing as a minimum:

- Certification of conformance
- Reference to wire purchase specification
- Overall diameter
- Insulation cures data
- Lubrication data
- Mechanical properties

4. PHYSICAL AND ELECTRICAL INSPECTION FOR FINISHED COILS

Materials and dimensions shall be as specified in Appendix I, attached.

All (100 % of) coils shall be exposed to 140 °C minimum for 3 hours minimum. This high-temperature storage may be performed prior to application of protective coating. After completion of this high-temperature storage, all (100 % of) finished coils shall be tested for conformance to physical parameters and electrical parameters as specified in Appendix I. Any of the following visual defects shall also be cause for rejection (10 x magnifications):

- Coating that is not cured to a tack free condition
- Coating with thickness insufficient to fill valleys between individual winding wires
- Coating that has pulled away or pulls away from the lead wires
- Coating with any bubble that has a dimension exceeding twice the end disc thickness
- Coating with any bubble that is broken
- Foreign material in contact with any wire, including lead wires and winding
- Foreign material that is not completely embedded
- Foreign material, or intentional material, outside the end disc diameter that renders the overall dimension of the coil, out of specification
- Lead connection with any loop or solder bridging between the lead wire and the winding wire
- Lead connection without at least one complete wrap of the winding wire around the lead wire
- Lead with any damage to insulation (where insulation is designed to be present)
- Lead with any damage to wire
- Winding turn displaced or moved from its correct wound position
- Winding with any damage to insulation (where insulation is designed to be present)
- Winding with any damage to wire

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- Winding with any unsupported wire (leaving visible space between winding and coil body) except at connection to lead
- Bent core–end discs or washers

Nota: The specified opaque coating may allow small clear areas where the imbedded colorant is absent. This is acceptable, provided there remains a sufficient coating of the base material on all areas of the coil.

5. QUALITY CONFORMANCE INSPECTION

5.1. AT SUPPLIER

Supplier shall perform quality conformance inspection for each lot in accordance with MIL–STD–105E, Level II, to meet acceptance quality levels (AQL) below. Supplier shall maintain records showing the lot number, lot size, number inspected, and number rejected.

AQL for mechanical requirements: 1.5 %.

AQL for electrical requirements: 1.0 %.

5.2. AT CUSTOMER

At receipt, customer will perform quality conformance inspection for each lot, in accordance with Appendix B of Mil M 38510 statistical, sampling, test and inspection procedures, to verify LTPD 20 with conditions listed below:

- Visual inspection at 20 X magnification and 40X in case of defect suspicion
- Criteria are those of the present document § 4
- Notification of lot rejection must be provided with 10 business days from receipt of order, and must include clear reason for rejection
- Return shipment must include supplier’s RMA number and ship date with 5 days from receipt of RMA number
- With the exception of lots rejected on incoming inspection with LTPD = 20, returns for visual defects will not be accepted for credit unless the defect is visible at 10X per specification

6. TRACEABILITY REQUIREMENTS

Supplier shall provide prior written notice to customer of any change in raw materials, manufacturing, or quality procedures that could affect product performance, reliability, or fitness for its intended use. Supplier may implement such change only after receipt of written approval from customer.

Each lot supplied to customer shall consist of coils with homogeneous raw materials, manufacturing procedures, and quality control. In particular, each lot shall consist of coils wound from the same wire lot. Whenever possible, minimum lot size shall be 100 coils.

Supplier shall complete and retain a lot traveler for each lot, identifying the wire lot, core assembly, and winding tension used. Winding tension shall conform to wire manufacturer's recommendations as indicated in wire purchase specification. Lot traveler shall also indicate for each manufacturing and inspection operation with a potential effect on finished coil quality, including quality conformance inspection:

- Operator identification
- Procedure
- Date completed
- Number of coils. For inspection operations, the number of accepted and rejected coils shall also be indicated

Records required by this specification shall be available for inspection by customer. Supplier shall retain them for a period of ten years minimum after shipment.

7. PACKAGING AND LABELING

The outer and inner packaging shall be adequate for shipment and handling without damage.

7.1. OUTER PACKAGING

The label and/or shipping invoice attached to the outside of each package shall provide at least the following information:

- Manufacturer's identification
- ELA specification number
- Shipping date
- Quantity of coils

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7.2. INNER PACKAGING

Each inner package label shall provide at least the following information:

- Manufacturer's identification
- Ela specification number
- Manufacturer's part number
- Lot number
- Wire lot number
- Quantity of coils
- QA acceptance
- Date of manufacture

7.3. CERTIFICATE OF CONFORMANCE

Supplier shall furnish a certificate of compliance with each shipment.

This shall identify:

- Ela purchase order number
- Ela specification number
- Manufacturer's part number
- Shipment date
- Lots numbers
- Quantity per lot

8. ELECTRICAL, MECHANICAL AND PHYSICAL REQUIREMENTS

Parameter	Nominal Value	Min	Max	Note
Coil, external wire and solder characteristic				
Overall diameter	-	-	4.29mm	T
Overall height	-	-	3.60mm	T
External solderable wire length	45mm,			
External solderable wire ends stripped	4.8mm			
External solderable lead wire overall diameter	0.14mm			
External lead wire color (start winding)	GREEN			
External lead wire END color (finished winding)	RED			
lead and coil wire solder material	Sn96Ag4%			
Electrical specifications				
Inductance L_0 @ 1KHz / 1Vpp	120mH	102mH	138mH	T
Serial resistance @ 1KHz / 1Vpp	345 Ω	295 Ω	395 Ω	T
Quality factor	-	1.8	-	C
Inductance @ 1.2mT DC field	-	L_0 -20%	-	Q
Inductance @ 4.0mT DC field	-	-	L_0 -20%	Q

- Q means performed on end-of-line lot qualification
- T means 100% tested in production
- C means calculated