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STANDARD FOR VASCULAR IMPLANTS – PRD018

1. SCOPE

This specification covers the requirements applicable to tubing with an outer diameter ≤ 15mm (≤ 0.6") supplied by MINITUBES to manufacturers vascular stents in common medical grade materials or vascular device with similar functional needs. More specific materials (Phynox®, tantalum, custom alloys, …) or specific applications can be discussed with our Sales Department.
It does not give any guarantee regarding the ability of the tubing to perform adequately in its intended usage, which remains the full responsibility of the device manufacturer.
It aims at defining a precise contractual basis between MINITUBES and its customers.
It defines the standard prescriptions applicable to criteria not specific elsewhere.

Our sales department is at the customer's disposal to discuss their specifications in order to best meet their needs.

Document ranking :

- level 1 : customer specification, if any
- level 2 : this specification

2. REFERENCE DOCUMENTS

International standards on each used raw material (see table / 7.2)

3. REGULATORY REQUIREMENTS

Any regulatory requirements potentially impacting the supply shall be notified to MINITUBES explicitly and be part of the requirements specified by the customer.

4. INFORMATION FEEDBACK

Customers are required to notify MINITUBES of all incidents or risks of incidents linked to our supply, to allow the initiation of adequate corrective and preventive actions.

5. MANUFACTURING CONTROL

Medical products are manufactured according to ISO 13485 compliance rules.
MINITUBES shall notify customers of any process change potentially affecting the form, fit and function of the device.

Classified clean rooms are not being used.

6. REQUIREMENTS ON THE RAW MATERIAL

6.1 General requirements :

The raw material is purchased by MINITUBES according to its proprietary purchasing specification (specific to each material) and has to meet the requirements of the international standards on each used raw material.
MINITUBES shall request documented certification from its material supplier and will check compliance by a certification from an independent laboratory, on each ingot of raw material.

6.2 Chemical composition :

The heat analysis shall conform to the international standard on the used material.

7 REQUIREMENTS ON THE PRODUCT IN ITS SUPPLIED FORM

As an additional guarantee that MINITUBES' process did not alter the melt properties, MINITUBES also checks the conformity of the product in its supplied form, to the following requirements.

7.1 Description :

Minitubes description	UNS description	International description
Alloy per ASTM F138 and ISO 5832.1	S.31673	Fe-18Cr-14Ni-2.5Mo
Alloy per ASTM F562 and ISO 5832.6	R.30035	Co-35Ni-20Cr-10Mo
Alloy per ASTM F90 and ISO 5832.5	R.30605	Co-20Cr-15W-10Ni-1.5Mn

Other alloys :
Other medical grade materials like Phynox®, Tantalum, etc … are also available. Applicable standards and detailed properties are to be discussed on a case by case basis.

7.2 Metallurgical requirements :

Minitubes' description	Common name	Chemical composition	Absence of delta ferrite	Resistance to intergranular corrosion	Inclusions rate	Grain size
Alloy per ASTM F138 and ISO 5832.1	316L	C, Si, P, S, Mn, Ni, Cr, Mo, Cu, N	ASTM F138	ASTM A262 Practice E	ASTM E45 ISO 4967	ASTM E112 ISO 643
Alloy per ASTM F562 and ISO 5832.6	MP35N / 35N LT	C, Si, P, S, Mn, Ni, Cr, Mo, Ti, Fe, B	NA	NA	ASTM E45 ISO 4967[1]	ASTM E112 ISO 643
Alloy per ASTM F90 and ISO 5832.5	L605	C, Si, P, S, Mn, Ni, Cr, Fe, Mo, W	NA	NA	ASTM E45 ISO 4967	ASTM E112 ISO 643

NA = non applicable
The latest revision of above Standards applies
[1] Determination of inclusion content is not specified in ASTM F562 but performed by Minitubes to ensure product quality.

7.3 Mechanical properties and grain size :

Mechanical properties and grain size index as measured on the finished product shall comply with the following table. For more specific mechanical properties requirements or technical support, you may contact our Sales Department.

Minitubes description	Condition	Rm (MPA)	Rp 0.2 % (MPA)	A %	Grain Size ASTM
Alloy per ASTM F138 and ISO 5832.1	Hard drawn	≥ 900	≥ 650	≤ 20 %	≥ 6
	Annealed	≥ 600	≤ 380	≥ 40 %	≥ 6
Alloy per ASTM F562 and ISO 5832.6	Hard drawn	≥ 1300	≥ 900	≤ 20 %	≥ 6
Alloy per ASTM F90 and ISO 5832.5	Hard drawn	≥ 1500	≥ 900	≤ 20 %	≥ 6
	Annealed	≥ 1000	≤ 690	≥ 40 %	≥ 6

7.4 Dimensions, tolerances, surface finish and other features :

Criteria	Range	Tolerances
O.D.	Ø ≤ 3 mm	± 0.014 mm
	3mm < Ø < 5 mm	± 0.020 mm
	5mm ≤ Ø ≤ 15 mm	± 0.025 mm
Circularity	Ø ≤ 3 mm	≤ 0.005 mm
	3mm < Ø	Per tolerance of OD
Wall thickness	Wall Tickness ≤ 0.10 mm	± 0.010 mm
	Wall Tickness > 0.10 mm	± 10 % of nominal Wall Thickness
Concentricity	Wall Tickness ≤ 0.14 mm	≤ 0.014 mm
	Wall Tickness > 0.14 mm	≤ 10 % of nominal Wall Thickness
Inside roughness (Ra) Outside roughness (Ra)	≤ 0.6 µm ≤ 0.6 µm	/
Inside surface finish Outside surface finish	No deep drawing lines, tearing, scratches	/
Length	1400mm	± 600 mm
Straightness	The tubes have to roll down a 5° inclined table without any assistance other than to initiate the movement.	
Cleanliness	Absence of deposit and corrosion traces which could be observed with the naked eye	
Batch quantity	/	± 10 % of the ordered quantity

7.5 Other criteria or characteristics :

All other criteria not specified by the definition documents are not inspected.

8. INSPECTION PROCEDURE

Compliance of products to above requirements is based on Sampling Plans and Inspection Methods as described in our Inspection Procedure GC PRD018 at its latest revision (available on request).
The heavy samplings and accurate instruments used ensure reliable Inspection data and compliance.

9. PACKAGING

Tubing is packed inside plastic sockets and PVC case ensuring adequate protection and conservation under normal stocking and handling conditions.
Shipments are made in cardboard or wooden boxes.
Small parts are supplied in plastic bags properly sealed and packed in cardboard boxes.

10. DOCUMENTATION

Minitubes shall supply with each delivery a certificate of conformity, including:

- Lot number
- PO number
- Applicable specification
- Chemical properties
- Metallurgical properties
- Dimensional properties
- Surface properties

11. RECORD CONSERVATION

All documents and records related to QA are kept for 10 years with effect from the shipping date of the products.
If the life expectancy of the products requires a longer conservation of the data, the customer shall inform Minitubes.

12. QUALITY ASSURANCE

All manufacturing steps of implant tubing processing are according to our Quality Management Manual, Process Management, Operation Procedures and Work Instructions, in compliance with ISO 9001 and ISO 13485.
Our QA system is monitored through internal audits and audits by a certified body.
Customers audit of facility and organisation can be arranged on request.