



Doc #

CDC-05975

Revision

01

## STANDARD FOR THV TUBING

### 1. SCOPE

This document aims at defining a precise contractual technical basis between MINITUBES and its customers for the supply of metal tubing with an outer diameter greater than 15mm used for balloon expandable Transcatheter Heart Valve (THV) or other devices with similar functional requirements.

It defines MINITUBES standard prescriptions applicable to the attributes of the product not specified elsewhere.

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.

Our sales department is at the customer's disposal to take into account and 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 section 6.2)

### 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.

Written by

Alexis Darbouret

Approved by

Philippe Poncin

date

31/07/2021



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### 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.

Minitubes' description	Common name	International description	Absence of delta ferrite	Resistance to intergranular corrosion	Inclusions rate	Grain size
Alloy per ASTM F138 and ISO 5832.1	316L	Fe-18Cr-14Ni-2.5Mo	ASTM F138	ASTM A262 Practice E	ASTM E45 ISO 4967	ASTM E112 ISO 643
Alloy per ASTM F562 and ISO 5832.6	MP35N	Co-35Ni-20Cr-10Mo	N/A	N/A	ASTM E45 ISO 4967 <sup>1</sup>	ASTM E112 ISO 643

<sup>1</sup> Determination of inclusion content is not specified in ASTM F562 but performed by Minitubes to ensure product quality

For other alloys, please contact our Sales Department.

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### 7 REQUIREMENTS ON THE PRODUCT IN ITS SUPPLIED FORM

#### 7.1 Dimensional requirements

Criteria	Nominal Range	Tolerances
Outer Diameter	15 to 32 mm	± 0.3%
Wall thickness	0.45 to 0.7 mm	± 0.025 mm
Length	400mm – 2000 mm	

For dimensional requirements beyond above nominal range, please contact our Sales Department.

#### 7.2 Other criteria or characteristics

Criteria	Tolerances/Requirements
Straightness	The tubes have to roll down a 5° inclined table
Surface aspect	Clean and free of deep drawn lines
Condition	Hard drawn
Batch quantity	±10% of the ordered quantity

Tubes are supplied in hard drawn condition. For other conditions or specific mechanical properties, please contact our Sales Department.

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 PSP-03228 at its latest revision (available on request).

### 9. PACKAGING

Tubing is packed inside plastic sockets and PVC case ensuring adequate protection and conservation under normal stocking and handling conditions.

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Shipments are made in cardboard or wooden boxes suitable for air freight.

### 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. RECORDS RETENTION

All documents and records related to QA are kept for 10 years with effect from the shipping date of the products.

### 12. QUALITY ASSURANCE

THV tubing processing comply with 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.

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