STANDARD FOR SURGICAL IMPLANTS

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REGISTRATION OF MODIFICATIONS			
MODIF N°	DATE	SUBJECT	SIGNATURE
∅	25/11/99	CREATION DOCUMENT	
1	14/12/99	MODIF § 7.3.5	
2	28/02/01	MODIF §2 §6 §7 §11	
3	21/08/03	REWRITING	
4	27/01/04	MODIF §7.2	
5	18/06/04	MODIF §5	

SUMMARY

1. SCOPE :

This specification covers the requirements applicable to tubing supplied by MINITUBES to the manufacturers of surgical implants.
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 implant manufacturer.
Its object is to define a precise contractual basis between MINITUBES and its customers.
It defines the standard Minitubes prescriptions applicable to the non specified elements of the products.
Intended to meet implicit requirements, the indicated values can be significantly under the best possibilities.
Our sales department is at the customers' disposal to take into account and to discuss their specifications in order to best meet their needs.

2. REFERENCE DOCUMENTS:

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

3. REGULATORY REQUIREMENTS :

If regulatory requirements concerning the products have any impact on the supply, they have to be notified to us explicitly and be part of the requirements specified by the customer.

4. INFORMATION FEED-BACK :

Regarding vigilance referring to material,customers arre required to notify us 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 compliant rules. Process changes are allowed, as long as they do not affect the specified requirements, unless otherwise notified by the customers.
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 batch of raw material ordered.

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 :

7.1 Description :

Minitubes description	UNS description	International description
1 Alloy per ASTM F.138 and ISO 5832.1	S.31673	Fe-18Cr-14Ni-2.5Mo
2 BIODUR 108		Fe-23Mn-21Cr-1mo-1N
3 Alloy per ASTM F562and ISO 5832.6	R.30035	Co-35Ni-20Cr-10Mo
4 Alloy per ASTM F90 and ISO 5832.5	R.30605	Co-20Cr-15W-10Ni-1.5Mn
5 Alloy per ASTM F1314	S.20910	Fe-22Cr-12.5Ni-5Mn-2.5Mo
6 Alloy per ASTM F1058 and ISO 5832.7	R.30008	Co-19Cr-17Ni—14Fe-7Mo-1.5Mn

7.2 Metallurgical requirements :

Minitubes description	Chemical composition	Absence of delta ferrite	Resistance to intergranular corrosion	Inclusions 'rate	Grain size
1 Alloy per ASTM F.138 ISO 5832.1	C, Si, P, S, Mn, Ni, Cr, Mo, Cu, N	ASTM F138	ASTM A262 Practice E	ASTM E45 ISO 4967	ASTM E112 ISO 643
2 BIODUR 108	C, Si, P, S, Mn, Ni, Cr, Mo, Cu, N	/	/	ASTM E45 ISO 4967	ASTM E112 ISO 643
3 Alloy per ASTM F562 ANDISO 5832.6	C, Si, P, S, Mn, Ni, Cr, Mo, Ti, Fe, Co, B	/	/	ASTM E45 ISO 4967	ASTM E112 ISO 643
4 Alloy per ASTM F90 AND ISO 5832.5	C, Si, P, S, Mn, Ni, Cr, Fe, Mo, W	/	/	ASTM E45 ISO 4967	ASTM E112 ISO 643
5 Alloy per ASTM F1314	C, Si, P, S, Mn, Ni, Cr, Mo, N, Nb, V	/	/	ASTM E45 ISO 4967	ASTM E112 ISO 643
6 Alloy per ASTM F1058 AND ISO 5832.7	C, Si, P, S, Mn, Ni, Cr, Mo, Co, N	/	/	ASTM E45 ISO 4967	ASTM E112 ISO 643

7.3 Mechanical properties :

The physical conditions is stated on the order or in the customer's specification. Minitubes will measure the obtained mechanical properties (Rm, Rp 0.2 %, A %). The values in the table are typical features stated just for information and are not a contractual requirement. Contractual requirements are stated onthe order or on the customer specification.

Minitubes description	Condition	Rm (MPA)	Rp 0.2 % (MPA)	A %	Density (g/cm^3)
1 Alloy per ASTM F.138 ISO 5832.1	Hard drawn	935	760	5 %	7.95
	Annealed	670	340	> 40 %	
2 BIODUR 108	Annealed	1 050	741	25 %	8.53
3 Alloy perASTM F562 and ISO 5832.6	Hard drawn	1 400	990	4 %	8.43
	Annealed	940	500	> 40 %	
4 Alloy per ASTM F90 and ISO 5832.5	Annealed	> 965	> 483	> 40 %	9.10
5 Alloy per ASTM F1314	Annealed	827	448	> 40 %	7.88
6 Alloy per ASTM F1058 and ISO 5832.7	Hard drawn	1 450	1 300	8 %	8.30
	Annealed	950	450	> 40 %	

7.4 British units:

Minitubes description	Condition	Rm (Ksi)	Rp 0.2 % (Ksi)	A %	Density (g/in^3)
1 Alloy per ASTM F.138 ISO 5832.1	Hard drawn	135.7	110.3	5 %	130.28
	Annealed	97.2	49.3	> 40 %	
2 BIODUR 108	Annealed	152.4	107.5	25 %	139.78
3 Alloy perASTM F562 and ISO 5832.6	Hard drawn	203.2	143.7	4 %	138.14
	Annealed	136.4	72.6	> 40 %	
4 Alloy per ASTM F90 and ISO 5832.5	Annealed	140.1	70.1	> 40 %	149.13
5 Alloy per ASTM F1314	Annealed	120.0	65.0	> 40 %	129.13
6 Alloy per ASTM F1058 and ISO 5832.7	Hard drawn	210.4	188.7	8 %	136.01
	Annealed	137.9	65.3	> 40 %	

7.5 Dimensions, tolerances, surface finish and other features :

Criteria	Range	Tolerances
O.D.	Ø < 3.00 mm	± 0.015 mm
	3.00 < Ø < 5.00 mm	± 0.020 mm
	5.00 ≤ Ø ≤ 15 mm	± 0.025 mm
Circularity	Ø < 3.00 mm	< 0.005 mm
	3.00 < Ø 5.00 mm	Within OD tolerances
	5.00 ≤ Ø ≤ 15 mm	Within OD tolerances
Wall thickness		± 10 % from nominal value with mini tolerance 0.01 mm
Concentricity		= 7 % from nominal wall thickness with mini limit 0.01 mm
Inside roughness Outside roughness	< 0.8 µ	/
Inside surface finish Outside surface finish	Absence of drawing scratches visible under magnification X 15	/
Length	1 to 3 meters	/
Straightness	The 2 meters maxi tubes have to roll down the totality of an inclined place at 5 % without assistance (a slight movement is tolerated to start the rotation of the tubes) The tubes > 2 meters are visually tested on the table. A slight run-out is tolerated during the rotation of the tubes	
Cleanliness	The tubes have a final cleaning and their cleanliness is appraised by the absence of deposit and corrosion traces whiche could be observed with the naked eye.	
Quantity	/	± 10 % of the ordered quantity

Sampling and inspection methodes are defined in the inspection schedule of the annex.

7.6. Other criteria or characteristics :

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

8. PACKAGING :

Tubing are shipped within a plastic tubes then within PVC case ensuring adequate protection and conservation under normal stocking and handling conditions.
Small pieces are delivered in bulk in variable batch size, in new polyethylene bags and cardboard boxes.

9.DOCUMENTATION :

MINITUBES shall supply with each delivery:

- extra requirements specified by the customer
- inspection report : shows actual values for specified dimensions, surface finish
- certificate of conformity according to ISO 4990
- test report : states the results of the tests performed on the raw material and the finished product
  * chemical composition of the heat according to the certificate of the supplier
  * certification number of the independent laboratory
  * chemical composition of the product in its delivery condition
  * test results (see table / 7.2)

10. RECORD CONSERVATION :

The totality of the documents and records related to quality is conserved 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 should inform us.

11. INSPECTION PLAN :

See attachment
The ANSi ASQC Z1.4 and NFX 06.022 norms are not well suited in case of tubes in length and no current standard complies correctly with this case.
The following features are conventionally applied:
Batch size: 1 piece = 1 tube.
Sampling 1 inspected piece = 1 area inspected on the tube (middle or one of its extremities)

12. SYNOPTIC AND ASSOCIATED PROCEDURES :

PHASES	INTERNAL DOCUMENTATION
Product definition	PRD018 and (or) customer specification
Customer requirement translation	ORG057
Manufacturing schedule preparation	ORG057
Inspection schedule preparation Means of inspection arrangements	F.I.217 ORG010
Product manufacturing	FAB036 or specific procedure for an item to be qualified
No-conformity management	ORG001
Medical devices	ORG050 ORG051