

INSPECTION SCHEDULE

N° G.C.PRD018

CUSTOMER REF. : Surgical implants		CUSTOMER :	
MINITUBES REF. :		WRITTEN BY : Mr JABOUIN	APPROVED BY :
IND.	MODIFICATIONS	DATE	SIGNATURE
Ø	CREATION of DOCUMENT	25/11/99	
5	MODIF MECHANICAL PROPERTIES	20/09/04	
6	REWRITING	28/09/05	

QUALITY LEVELS

- 1 → 1 inspection per batch of material
 2 → 2 samples per production run (A=0 R=1)
 3 → 1 inspection per fabrication run
 4 → 1 measurement per batch
 5 → Level S4 AQL 0.65 % Normal Inspection Single Sampling Plan ANSI/ASQC Z1.4.1993
 6 → Level S3 AQL 1.50 % " " " " " " " "

Warning : precautionary measures

- tubing must be handled with care to avoid any scratch, bend, distorsion
- Before sampling the tubes from a bundle, the bundle must be intied and the tubes spread on the work area (do not remove a tube from a tied bundle)
- After cutting, ensure residual burs will not scratch the tubes.

(*) NOTA : inspection performed on tubing in manufacturing lengths before cutting to final length

CODE	QUAL LEV.	MESURED BY	OBSERVATIONS
Raw material			
Metallurgical test (*)	1	Laboratory	See PRD018 except inclusion's test 3 samples
Finished product			
Metallurgical tests	3	Laboratory	See PRD018
Grain size	3	LEICA microscope	Transverse specimen if final state # annealed Longitudinal specimen if final state = annealed
Mechanical properties	2 tests conf.	Inhouse INSTRON tensile	6 mandrels 45 mm radius Sample length 200 mm Extensometer 50 mm Speed 10 MPA/ sec.except L605 (12.7 mm par minute) Confirmed = homogeneous and non broken in jaws Wall thickness calculated by weight in order to determine cross section
Hardness	4	Microdurometer	

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CODE	QUAL LEV.	MESURED BY	OBSERVATIONS
ID (*)	5	Go / no go gauges	
OD (*) Circularity	5	Laser micrometer	As per DOCQ.096, 3 measurements per section, 2 sections per tube at each end At the same time diameter (\varnothing max – \varnothing min) / 2
Wall thickness (*)	5	Vertical comparator or HEIDENHAIN	As per DOCQ.097 4 measurements per section, 1 section per tube
Concentricity			At the same time wall thickness (Wt max – Wt min)
ID Roughness (Ra) OD Roughness (Ra)	6	Roughnesstester Roughnesstester	Cut off 0.25 X 1 Cut off 0.25 X 1
ID Surface finish (*)	5	Magnifier X 15	At both extremities, absence of drawing scratches
OD Surface finish (*)	Unit	Magnifier X 15	See standard defects table
Length	5	Rule	
Straightness	Unit.	Inspection table inclined at 5°	The tubes have to roll down the totality of the inclined plane without assistance (a slight movement is tolerated to start rotation)
Cleanliness	5	Naked eye	Absence of residue, particles, corrosion traces