TC 150

International Standard 5832/1

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

Implants for surgery — Metallic materials — Part 1 : Wrought stainless steel

Implants chirurgicaux — Produits à base de métaux — Partie 1 : Acier à forger inoxydable

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 5832/1 was developed by Technical Committee ISO/TC 150, *Implants for surgery*, and was circulated to the member bodies in April 1978.

It has been approved by the member bodies of the following countries :

Australia	India	South Africa, Rep. of
Belgium	Ireland	Spain
Canada	Italy	Switzerland
Czechoslovakia	Mexico	USA
France	New Zealand	USSR
Germany, F. R.	Romania	

The member body of the following country expressed disapproval of the document on technical grounds :

Austria

Implants for surgery — Metallic materials — Part 1 : Wrought stainless steel

1 Scope

This International Standard specifies the characteristics of, and corresponding test methods for, wrought stainless steel for use in the manufacture of surgical implants.

Provision is made for two types of stainless steel based on composition (see table 1).

NOTE — The mechanical properties of a sample obtained from a finished product made of this alloy may not necessarily comply with those specified in this International Standard.

2 Field of application

The lower carbon steel (composition B) is intended for the manufacture of implants of a permanent nature. The higher carbon steel (composition A) is suitable for the production of higher strength surgical implants such as wires and pins.

3 References

ISO 82, *Steel — Tensile testing.*

ISO 86, *Steel — Tensile testing of sheet and strip less than* 3 mm *and not less than* 0,5 mm *thick.*

ISO/R 377, *Selection and preparation of samples and test pieces for wrought steel.*

ISO/R 404, *Steel and steel products — General technical delivery requirements.*[1)]

ISO/R 437, *Chemical analysis of steels — Determination of total carbon (Gravimetric method after combustion in a stream of oxygen).*

ISO/R 439, *Chemical analysis of steel — Determination of total silicon (Gravimetric method).*

ISO/R 629, *Chemical analysis of steels — Determination of manganese (Spectrophotometric method).*

ISO/R 643, *Micrographic determination of the austenitic grain size of steels.*

ISO/R 671, *Chemical analysis of steel and cast iron — Determination of sulphur (Method after combustion in a current of oxygen and titration with sodium borate).*

ISO 2732, *Steels and cast iron — Determination of phosphorus — Spectrophotometric method.*

ISO 3651/2, *Austenitic stainless steels — Determination of resistance to intergranular corrosion — Part 2 : Corrosion test in a sulphuric acid/copper sulphate medium in the presence of copper turnings (Monypenny Strauss test).*

ISO 4967, *Steel — Determination of content of non-metallic inclusions — Micrographic method using standard diagrams.*

4 Chemical composition

4.1 Test samples

The selection of samples for analysis shall be in accordance with the provisions of ISO/R 377.

4.2 Cast analysis

The cast analysis of the steel shall comply with the relevant chemical composition specified in table 1 (for test methods, see clause 8).

Table 1 — Chemical composition

Element	Compositional limits, %	
	Composition A	Composition B
Carbon	0,08 max.	0,03 max.
Silicon	1,00 max.	1,00 max.
Manganese	2,00 max.	2,00 max.
Nickel	10,0 to 14,0	10,0 to 16,0
Chromium	16,0 to 19,0	16,0 to 19,0
Molybdenum	2,0 to 3,5	2,0 to 3,5
Sulphur	0,015 max.	0,015 max.
Phosphorus	0,025 max.	0,025 max.
Copper	0,50 max.	0,50 max.
Iron	Balance	Balance

1) At present at the stage of draft. (Revision of ISO/R 404-1964.)

5 Microstructure in fully annealed condition

5.1 Grain size

The austenitic grain size determined as specified in clause 8 shall be no coarser than grain size No. 4.

5.2 Absence of delta ferrite

The steel shall have a structure free from delta ferrite when examined as described in clause 8.

5.3 Inclusion content

The non-metallic inclusion content of the steel, determined at the billet stage, from a billet not exceeding 15 cm thickness, and as specified in clause 8, shall not exceed the limits given in table 2.

NOTE — It may be necessary to use a special manufacturing technique such as vacuum or electroslag melting to produce a steel complying with these cleanliness requirements.

Table 2 — Inclusion content limits

Type of inclusion	Inclusion content	
	Thin	Thick
A — Sulphides	1,5	1,0
B — Aluminates	1,5	1,0
C — Silicates	1,5	1,0
D — Oxides, globular	1,5	1,0

6 Corrosion resistance

The steel, in the as delivered condition, shall be capable of passing the intergranular Monypenny Strauss corrosion test specified in clause 8.

7 Mechanical properties

7.1 Test pieces

The selection and preparation of samples and test pieces for tensile testing shall be in accordance with the provisions of ISO/R 377.

7.2 Tensile test

The tensile properties of the steel in the form of bars, wires, and sheet and strip, determined as specified in clause 8, shall be in accordance with the requirements of tables 3, 4 and 5 respectively.

Should any of the test pieces not meet the specified requirements or break outside the gauge limits, retests shall be carried out in accordance with the provisions of sub-clause 6.5 of ISO/R 404.

8 Methods of test

The methods of test to be used in determining compliance with the requirements of this International Standard shall be those given in table 6.

Table 3 — Mechanical properties of bars

Condition	Steel composition	Diameter or thickness	Ultimate tensile strength min.	Yield strength (0,2 % offset) min.	Elongation min.
		mm	MPa	MPa	%
Annealed	A	all	515	205	40
	B	all	480	170	40
Cold finished	A	up to 13 incl.	620	310	35
	B	up to 13 incl.	605	295	35
	A	over 13	515	205	35
	B	over 13	505	195	35
Cold worked (high tensile)	A and B	up to 19 incl.	860	690	12
	A and B	over 19 to 25	790	550	15
	A and B	over 25 to 32	725	450	20
	A and B	over 32 to 38	690	345	28
	A and B	over 38 to 44	655	310	28

Table 4 — Mechanical properties of wires
(for both steel compositions)

Condition	Diameter	Ultimate tensile strength min.	Elongation min.
	mm	MPa	%
Annealed	0,025 to 0,127 incl.	1 000	30
	over 0,127 to 0,229	930	30
	over 0,229 to 0,381	890	35
	over 0,381 to 0,508	860	40
	over 0,508 to 0,635	820	40
	over 0,635 to 0,889	790	40
	over 0,889 to 1,09	760	45
	over 1,09	730	45
Cold drawn[1)]	0,762 to 3,18	830 to 1 035	15
	over 3,18	760 to 965	15

1) Wire ordered in the cold drawn condition can be supplied to higher tensile strength levels as specified by the purchaser.

Table 5 — Mechanical properties of sheet and strip

Condition	Steel composition	Ultimate tensile strength min.	Yield strength (0,2 % offset) min.	Elongation min.
		MPa	MPa	%
Annealed	A	500	205	40*
	B	450	170	40*
Cold finished	A	620	315	35
	B	610	300	35
Cold worked	A	860	690	12
	B	860	690	12

* For thickness under 3 mm : 38 %.

Table 6 — Methods of test

Requirement	Relevant clause or sub-clause	Method of test
Chemical composition	4	
Carbon		ISO/R 437
Silicon		ISO/R 439
Manganese		ISO/R 629
Sulphur		ISO/R 671
Phosphorus		ISO 2732
Other elements		Recognized analytical procedures (ISO methods where these exist)
Grain size	5.1	ISO/R 643 NOTE — It is preferred that samples for grain size determination be selected after the last annealing operation and prior to final cold-working operation. If samples are selected after a final cold-working operation, transverse specimens shall be prepared.
Absence of delta ferrite	5.2	a) Metallographically prepare specimens in the annealed condition from longitudinal and transverse sections. b) Using recognized techniques, examine the specimens at 100 X magnification for the presence or absence of delta ferrite.
Inclusion content	5.3	ISO 4967, Method A, Plate II
Corrosion resistance	6	ISO 3651/2
Mechanical properties	7	
Ultimate tensile strength Yield strength Elongation		ISO 82 or ISO 86, as appropriate to the form of the steel