

**Rolled and wrought stainless steel products
for surgical implants**
Technical delivery conditions

DIN
17 443

Walzwerks- und Schmiedeerzeugnisse aus nichtrostenden Stählen
für chirurgische Implantate; technische Lieferbedingungen

Supersedes October 1977 edition.

In keeping with current practice in standards published by the International Organization for Standardization (ISO), a comma has been used throughout as the decimal marker.

See Explanatory notes for connection with International Standard ISO 5832/1 - 1980 published by the International Organization for Standardization (ISO).

Clauses and subclauses marked with a single dot ● give specifications which are to be agreed upon at the time of ordering. Subclauses marked with two dots ●● give specifications which are optional and may be agreed upon at the time of ordering.

1 Scope and field of application

1.1 This standard deals with stainless steels used in the manufacture of surgical implants, and gives details of their product forms and properties in the condition as delivered to the implant manufacturer.

1.2 The purpose of the standard is to ensure that implants are only manufactured from stainless steel grades that can, on the basis of present knowledge and clinical experience, be regarded as biologically compatible and as adequately resistant to corrosion when implanted in the living organism.

This standard is also designed to ensure that implants, such as plates and screws, including those originating from different manufacturers, can be connected to one another without risk of contact corrosion, provided that they have been manufactured in accordance with this standard.

1.3 A distinction is to be made between steels for implants and steels for medical instruments, which are specified in DIN 17 442.

1.4 Unless otherwise specified below, the general technical delivery conditions for steel and steel products given in DIN 17 010 shall apply.

2 Concepts

2.1 Stainless steels

Although steels with a chromium content of not less than 12% by mass and a carbon content not exceeding 1,2% by mass are generally considered to be stainless steels, stricter specifications apply in respect of the analysis limits for stainless steels used in the manufacture of implants (see table 1).

2.2 Product forms

The definitions given in EURONORM 79 shall apply for the product forms.

3 ● Dimensions and permissible dimensional deviations

The dimensions and the permissible dimensional deviations shall be agreed at the time of ordering, reference being made, if possible, to the appropriate dimensional standards listed in Appendix A.

4 Designation and ordering

4.1 The standard designation for steel complying with this standard, shall give in the following order:

- the name of product (steel);
- the number of this standard;
- the symbol or material number denoting the steel grade (see table 1)¹⁾;
- the symbol denoting the type of condition (see subclause 6.6, tables 3 and 7);
- the code letter denoting the treatment condition (see subclause 6.2), where applicable.

Example 1:

Steel DIN 17 443 - X 2 CrNiMo 18 15 3 m
or
Steel DIN 17 443 - 1.4441 m

Example 2:

Steel DIN 17 443 - X 2 CrNiMo 18 15 3 f K 860
or
Steel DIN 17 443 - 1.4441 f K 860

4.2 The specifications given in the relevant dimensional standards shall apply for the standard designation of the products.

4.3 The order shall provide any information necessary for a clear description of the required products including their composition and test methods to be applied. Should in certain cases the designations as in subclauses 4.1 and 4.2 not be adequate for this purpose, for example in the case of agreements as provided for in clauses and subclauses marked with ● or ●●, the required information shall be added to these designations.

5 Synopsis of steel grades and selection criteria

Table 3 gives a synopsis of the steel grades standardized for surgical implants, of their as delivered conditions and types of condition, and specifies the product forms and the dimensional standards normally applicable to the products

¹⁾ *DIN-Normenheft* (DIN Standardization Booklet) No. 3 provides information on how the symbolic designations and material numbers of steels are formed.

Continued on pages 2 to 11

to be supplied, and the types of implants for which the steel grades concerned are generally and preferably used. As regards the selection of steel grade, form and dimensions, as delivered condition and type of condition of the starting product used in the manufacture of implants, certain factors may have to be taken into account, such as the facilities of the manufacturer, which cannot be given full consideration in a standard. Consequently, compliance with the specifications given in this standard in no way relieves the implant manufacturer of his responsibility to decide upon the proper selection of the starting product which has the characteristics best suited to the application intended. Before a final decision is made, it should be checked whether the relevant implant standards include additional information reflecting the latest state of the art, which has a bearing on the selection of steel.

6 Requirements

6.1 Manufacturing process

6.1.1 The steel shall be manufactured by employing a special melting process, such as remelting using the vacuum arc remelting process or the electroslag remelting process, the choice of the melting process being at the manufacturer's discretion.

6.1.2 The shaping process shall also be at the manufacturer's discretion.

6.2 As delivered condition

See tables 3 to 7 (and subclause 6.6) for the customary treatment condition on supply.

● In cases where both the K 860 treatment condition and the K treatment condition are possible for the types of condition f, o or p, the required treatment condition shall be specified in the order.

6.3 Chemical composition

6.3.1 The values specified in table 1 shall apply for the chemical composition as determined by the cast analysis. Minor deviations from the limit values shall be permitted provided that the performance characteristics of the steel, and its chemical resistance in particular, are not adversely affected.

6.3.2 The product analysis may deviate from the limit values determined by the cast analysis by the amounts specified in table 2.

6.4 Resistance to intergranular corrosion

The steels shall be resistant to intergranular corrosion in the as delivered condition.

Note. Proof as furnished for the resistance in the as delivered condition also applies for the condition in use, provided that only minor cold working operations (such as bending) or machining are to be carried out.

6.5 Mechanical properties

The values specified in tables 4, 5 and 6 shall apply for the mechanical properties in the solution annealed, K 860 type and K type as delivered conditions.

Note. A higher strength than that specified for the solution annealed condition shall not be attained except by the process of cold working (drawing, rolling).

6.6 ● Type of condition

The products may be delivered in one of the types of condition specified in tables 3 and 7, depending on the order. The condition of the products on delivery and the most suitable type of condition for each individual application concerned should be agreed with the manufacturer's works. Slight irregularities in the surface resulting from the manufacturing process are permitted, except for type of condition p.

6.7 Structure

6.7.1 Delta ferrite

The steels shall have a structure free from delta ferrite when tested as described in table 8.

6.7.2 Grain size

The grain size shall correspond at least to grain size index 4 as specified in DIN 50 601, in the condition after the final heat treatment (solution annealing), and prior to the cold working process required to achieve the specified strength corresponding to the K or K 860 type treatment condition.

6.8 Non-metallic inclusions (degree of purity)

The micrographs of non-metallic inclusions obtained when testing as specified in table 8 shall be at least equal to or better than the diagrams reproduced in DIN 50 602, standard diagram plate 1 specified below:

- sulfide inclusions: diagram 0.1 or 1.1;
- aluminium oxide inclusions: diagram 2.2 or 3.1;
- oxide inclusions of elongated type: diagram 5.3 or 6.2;
- oxide inclusions of globular type: diagram 8.2 or 9.3.

7 Testing

7.1 Scope of test, sampling and test procedure

The details given in table 8 shall apply.

7.2 ● Test certificate

An inspection certificate as specified in DIN 50 049 shall be issued in respect of the results of testing carried out as shown in table 8. The type of inspection certificate required shall be specified in the order.

8 Complaints

8.1 Under current law, warranty claims may only be raised against defective products if defects impair their processing and use to a more than negligible extent. This shall apply unless otherwise agreed at the time of ordering.

8.2 It is normal and practical for the purchaser to give the supplier the opportunity to judge whether the complaints are justified, if possible by submitting the product objected to or samples of the product supplied.

Table 1. Steel grades and their chemical composition as determined by the cast analysis

Steel grade		Chemical composition, % by mass										
Symbol	Material number	C	Si	Mn	P	S	N	Cr ^{?)}	Mo ^{?)}	Ni	Nb	
		max.	max.		max.	max.						
X 2 CrNiMoN 18 13 3	1.4428	0,030	1,0	max. 2,0	0,025	0,010	0,14 to 0,22	17,0 to 18,5	2,7 to 3,2	13,0 to 14,5		
X 2 CrNiMo 18 15 3	1.4441	0,030	1,0	max. 2,0	0,025	0,010	max. 2,0	17,0 to 18,5	2,7 to 3,2	13,5 to 15,5		
X 2 CrNiMoN 18 15 4	1.4442	0,030	1,0	max. 2,0	0,025	0,010	0,10 to 0,20	17,0 to 18,5	3,7 to 4,2	14,0 to 16,0		
(X 2 CrNiMnMoN 22 13 6) ¹⁾	(1.4461) ¹⁾	0,030	0,75	5,5 to 7,5	0,025	0,010	0,35 to 0,50	21,0 to 23,0	2,7 to 3,7	10,0 to 16,0	0,10 to 0,25	

¹⁾ See Explanatory notes.

^{?)} The minimum chromium and molybdenum contents have been specified to give an effective proportion of the elements of not less than 26. This proportion is to be calculated from the following formula: $3,3 \times \% \text{ Mo} + \% \text{ Cr}$.

Table 2. Amounts by which the chemical composition as determined by the product analysis may deviate from the limit values given in table 1 for the cast analysis

Element	Limit value for the cast analysis % by mass	Permissible deviations ¹⁾ % by mass
Carbon (C)	$\leq 0,030$	+ 0,005
Silicon (Si)	$\leq 1,0$	+ 0,05
Manganese (Mn)	$\leq 2,0$ $> 2,0 \leq 7,5$	+ 0,04 $\pm 0,10$
Phosphorus (P)	$\leq 0,025$	+ 0,005
Sulfur (S)	$\leq 0,010$	+ 0,005
Nitrogen (N)	$\leq 0,50$	$\pm 0,01$
Chromium (Cr)	$\geq 17,0 < 20,0$ $\geq 20,0 \leq 23,0$	$\pm 0,20$ $\pm 0,25$
Molybdenum (Mo)	$\geq 2,7 \leq 4,2$	$\pm 0,10$
Nickel (Ni)	$\geq 10,0 \leq 16,0$	$\pm 0,15$
Niobium (Nb)	$\leq 0,25$	$\pm 0,05$

¹⁾ For one cast, the deviation of an element as determined by the product analysis may only be either below the minimum value or above the maximum value of the range specified for the cast analysis, but not both at the same time. If maximum values only are specified, only positive deviations shall apply.

Table 4. Mechanical properties of bars and sections

Steel grade		As delivered condition (treatment condition)	Diameter or thickness (in the case of sections) mm	Minimum 0,2% proof stress N/mm ²	Tensile strength N/mm ²	Minimum elongation after fracture A ₅ %
Symbol	Material number					
X 2 CrNiMoN 18 13 3	1.4428	Solution annealed	All existing sizes	300	600 to 800	40
X 2 CrNiMo 18 15 3	1.4441			190	490 to 690	40
X 2 CrNiMoN 18 15 4 ¹⁾	1.4442 ¹⁾			285	590 to 800	40
X 2 CrNiMnMoN 22 13 6	1.4461			500	850 to 1050	35
X 2 CrNiMoN 18 13 3 X 2 CrNiMo 18 15 3 X 2 CrNiMoN 18 15 4 X 2 CrNiMnMoN 22 13 6	1.4428 1.4441 1.4442 1.4461	K 860 ²⁾	≤ 19	690	860 to 1100	12 ³⁾
		K	Subject to agreement.			

1) This steel is not available at present in the solution annealed condition; the values specified here are intended for information only.

2) This as delivered condition is not applicable to X 2 CrNiMnMoN 22 13 6 steel (1.4461).

3) For cross sections not exceeding 50 mm², a 50 mm gauge length is also permitted.

Table 5. Mechanical properties of wires

Steel grade		As delivered condition	Diameter, d mm	Tensile strength N/mm ²	Minimum elongation after fracture (L ₀ = 50 mm) %
Symbol	Material number				
X 2 CrNiMoN 18 13 3 X 2 CrNiMo 18 15 3 X 2 CrNiMoN 18 15 4 ¹⁾	1.4428 1.4441 1.4442 ¹⁾	Solution annealed	0,025 ≤ d ≤ 0,13	≤ 1000	30
			0,13 < d ≤ 0,23	≤ 930	30
			0,23 < d ≤ 0,38	≤ 890	35
			0,38 < d ≤ 0,50	≤ 860	40
			0,50 < d ≤ 0,65	≤ 820	40
			0,65 < d	≤ 800	40
X 2 CrNiMnMoN 22 13 6	1.4461	Solution annealed	0,025 ≤ d ≤ 0,13	≤ 1300	20
			0,13 < d ≤ 0,23	≤ 1260	20
			0,23 < d ≤ 0,38	≤ 1230	25
			0,38 < d ≤ 0,50	≤ 1200	30
			0,50 < d ≤ 0,65	≤ 1150	30
			0,65 < d	≤ 1100	30
X 2 CrNiMoN 18 13 3 X 2 CrNiMo 18 15 3 X 2 CrNiMoN 18 15 4 X 2 CrNiMnMoN 22 13 6	1.4428 1.4441 1.4442 1.4461	K	0,20 ≤ d ≤ 0,70	1600 to 1850	—
			0,70 < d ≤ 1,00	1500 to 1750	—
			1,00 < d ≤ 1,50	1400 to 1650	—
			1,50 < d ≤ 2,00	1350 to 1600	—

1) This steel is not available at present in the solution annealed condition; the values specified here are intended for information only.

Table 6. Mechanical properties of cold rolled sheet and strip

Steel grade		As delivered condition	Minimum 0,2% proof stress N/mm ²	Tensile strength N/mm ²	Minimum elongation after fracture (L ₀ = 80 mm) ¹⁾ %
Symbol	Material number				
X 2 CrNiMoN 18 13 3	1.4428	Solution annealed	300	600 to 800	40 ²⁾
X 2 CrNiMo 18 15 3	1.4441		190	490 to 690	40 ²⁾
X 2 CrNiMoN 18 13 3	1.4428	K	390	≥ 650	35
X 2 CrNiMo 18 15 3	1.4441		300	≥ 610	35
X 2 CrNiMoN 18 13 3 X 2 CrNiMo 18 15 3	1.4428 1.4441	K 860	690	860 to 1100	12

¹⁾ This gauge length applies for a 20 mm test piece width. In the case of narrower strips, a 50 mm gauge length in conjunction with a 12,5 mm test piece width is permitted.

²⁾ 38 % for thicknesses less than 3 mm.

Table 7. Type of condition and surface finish of products

Symbol ¹⁾	Type of condition	Surface finish	Product form			Notes
			Flat products	Wire	Steel bars	
b or Ic	Hot formed, heat treated ²⁾ , not descaled	Covered with rolling skin	X	X	X	Only suitable for components to be descaled or machined all over after manufacture.
c1 or IIa	Hot formed, heat treated ²⁾ , mechanically descaled	Metallically clean	X	X	X	● The nature of the mechanical descaling, e.g. grinding, blasting or peeling, depends on the product form and shall be at the manufacturer's discretion, unless otherwise agreed.
c2 or IIa	Hot formed, heat treated ²⁾ , pickled		X	X	X	
f or IIIa	Heat treated, mechanically or chemically descaled, and then cold formed	Smooth and bright, considerably smoother than in the case of condition c2 or IIa	X	X	X	Cold forming without any subsequent heat treatment modifies the properties, depending on the degree of deformation (cf. tables 4 to 6).
m or IIIId	Mechanically or chemically descaled, cold formed, bright annealed ³⁾ , or bright annealed ³⁾ and lightly cold rerolled or cold redrawn	Glossy and smoother than in the case of condition c2 or IIa	X	X	—	Particularly suitable for grinding and polishing.
n or IIIc	Mechanically or chemically descaled, cold formed, heat treated ²⁾ , pickled, bright drawn (drawn and polished)	Dull and smoother than in the case of condition c2 or IIa	—	X	X	The products in this condition are somewhat harder than those in condition m or IIIId; they are particularly suitable for grinding or polishing.
o or IV	Ground	● The type, degree and extent of the grinding or polish shall be agreed at the time of ordering.	X	—	X	Conditions b or Ic, c1 or IIa, f or IIIa, n or IIIc, m or IIIId are normally used as the initial condition.
p or V	Polished		X	X	X	

¹⁾ As in DIN 17 440, July 1985 edition, this standard gives two sets of symbols in this table, the reason being that the new letter symbols have not yet been universally adopted, and work is at present proceeding on an international system of symbols. There thus seemed little point in insisting on a conversion from one system to another at the present time.
²⁾ "Heat treated" in this context means the solution annealed condition as specified in tables 4 to 6.
³⁾ "Bright annealed" in this context means the solution annealed condition as specified in tables 4 to 6.

Table B. Tests to be carried out for acceptance inspection, acceptance units, scope of test, sampling and test methods

Item tested	Acceptance unit ¹⁾	Scope of test	Sampling	Test procedure
Chemical composition	S	1 test per acceptance unit	The test piece shall be taken from the unmelted ingot or semi-finished product	At the manufacturer's discretion ²⁾ .
Resistance to intergranular corrosion	S + A + W	1 test per acceptance unit	The test piece shall be taken from products in the as delivered condition. If the surface of the products in this condition is identical with the surface as used, the latter shall be tested. Otherwise, the test piece may be worked out of the product.	As described in DIN 50914 (without any sensitizing heat treatment).
Tensile strength	S + A + W	1 or more tests per acceptance unit	Longitudinal test pieces. In the case of flat products of less than 3 mm thickness, the test piece shall be taken as described in DIN 50114; in the case of other products, it shall be taken as specified in DIN 50125. ●● Subject to agreement at the time of ordering, the tensile test may be carried out over the entire cross section of the product in the case of bars and sections.	As described in DIN 50114, DIN 50145 or DIN 51210 Part 1.
Delta ferrite content	S + A + W	3 tests per acceptance unit	The test pieces shall be taken after the final solution annealing treatment.	Longitudinal microsection (parallel to the direction of forming) through the centre plane; magnification 100 : 1.
Grain size	S + A + W	3 tests per acceptance unit	The test pieces shall be taken after the final solution annealing treatment, and, if applicable, prior to a subsequent cold forming operation. Longitudinal microsection.	As described in DIN 50601; magnification 100 : 1.
Inclusions (degree of purity)	S	6 tests per acceptance unit (3 each from top and bottom of the unmelted ingot)	In the case of bars and sections made from billets (150 mm maximum edge length), the test pieces shall be taken prior to the final hot forming operation.	As described in DIN 50602; method M.

¹⁾ A = dimensions; S = cast; W = heat treatment.

²⁾ In cases of dispute, the specifications given in the *Handbuch für das Eisenhüttenlaboratorium* (Handbook for the ferrous metallurgy laboratory) shall apply (see list of "Standards and other documents referred to").

Standards and other documents referred to

- DIN 175 Polished round steel; dimensions, permissible deviations associated with ISO tolerance zone h9
- DIN 668 Bright round steel; dimensions, permissible deviations associated with ISO tolerance zone h11
- DIN 671 Bright round steel; dimensions, permissible deviations associated with ISO tolerance zone h9
- DIN 1013 Part 1 Steel bars; hot rolled round steel for general purposes; dimensions, permissible dimensional deviations and deviations of form
- DIN 2076 Round spring wire; dimensions, masses, permissible deviations
- DIN 4186 Part 1 Sieve bottoms, round metal wires; dimensions
- DIN 17 010 General technical delivery conditions for steel and steel products
- DIN 17 440 Stainless steels; technical delivery conditions for plate and sheet, hot rolled strip, wire rod, drawn wire, steel bars, forgings and semi-finished products
- DIN 17 442 Rolled, wrought or cast stainless steel products for medical instruments
- DIN 50 049 Materials testing certificates
- DIN 50 114 Testing of metallic materials; tensile test on sheet or strip less than 3 mm thick, without extensometer measurement
- DIN 50 125 Testing of metallic materials; tensile test pieces
- DIN 50 145 Testing of metallic materials; tensile test
- DIN 50 601 Metallographic examination; determination of the ferritic or austenitic grain size of steel and ferrous materials
- DIN 50 602 Metallographic examination; microscopic examination of special steels using standard diagrams to assess the content of non-metallic inclusions
- DIN 50 914 Testing the resistance of stainless steels to intergranular corrosion; copper sulfate/sulfuric acid method; Strauß test
- DIN 51 210 Part 1 Testing of metallic materials; tensile test on wires, without extensometer measurement
- DIN 59 381 Steel flat products; cold rolled strip made from stainless steels and from heat resisting steels; dimensions, permissible dimensional deviations, deviations of form and in mass
- DIN 59 382 Steel flat products; cold rolled wide strip and sheet made from stainless steels; dimensions, permissible dimensional deviations and deviations of form
- EURONORM 79 Definition and classification of steel products by shape and dimensions
- Handbuch für das Eisenhüttenlaboratorium*);
- volume 2: *Die Untersuchung der metallischen Stoffe* (Investigation of metallic materials); Düsseldorf 1966
- volume 2a (supplementary volume); Düsseldorf 1982
- volume 5 (supplementary volume);
- A 4.4 — *Aufstellung empfohlener Schiedsverfahren* (List of recommended arbitration procedures);
- B — *Probenahmeverfahren* (Sampling procedure);
- C — *Analysenverfahren* (Methods of analysis);
- latest edition in each case.
- DIN-Normenheft No. 3: *Kurznamen und Werkstoffnummern der Eisenwerkstoffe in DIN-Normen und Stahl-Eisen-Werkstoffblättern* (Symbols and material numbers for ferrous materials used in DIN Standards and Iron and steel material sheets)

*) Obtainable from: *Verlag Stahleisen mbH*, Postfach 82 29, D-4000 Düsseldorf 1.

Previous edition

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Amendments

The following amendments have been made in comparison with the October 1977 edition:

- a) All the steel grades previously specified have been superseded by new steel grades.
- b) The mechanical properties associated with the various as delivered conditions are now specified separately for bars including sections, for wires and for flat products.
- c) The tests to be carried out and the details relating to sampling and to the scope of test are now clearly specified in tabular form.
- d) Additional material has been included to enable this standard to be used independently of DIN 17 440 as a separate technical delivery condition.
- e) The standard has been harmonized with international standards projects (see Explanatory notes).

Explanatory notes

This standard is in agreement with International Standard ISO 5832 Part 1, Implants for surgery; metallic materials. Part 1: Wrought stainless steel. The properties specified in the ISO Standard, which relate to the applications concerned, such as the delta ferrite content, the grain size, the degree of purity, have now been included in the present standard, and they have led to certain restrictions and modifications in respect of the chemical composition as specified in DIN 17 440 for X 2 CrNiMo 18 14 3 (1.4435) and X 2 CrNiMo 17 13 3 (1.4429) steels, resulting in the allocation of new symbols and material numbers for the steel grades concerned.

Steel grade A specified in ISO 5832 Part 1 for use for implants of superior strength has not been included in the present standard, because it is generally only resistant to intergranular corrosion if it has been subjected to special heat treatment, and because the required strength of the steel grades listed in this standard can be attained by cold forming.

Steel grade A has been dropped from the scheduled revised version of ISO 5832 Part 1. The scheduled alterations to the chemical composition of the other steel grades listed in ISO 5832 have already been taken into account in the present standard.

X 2 CrNiMnMoN 22 13 6 (1.4461) steel which is given in brackets in tables 1 and 3, has been included on a provisional basis only, because it has not as yet been used in Germany in the manufacture of implants, but is being supplied to implant manufacturers abroad. It is intended to deal with this steel grade in a further Part of ISO 5832.

International Patent Classification

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