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Rolled, Wrought or Cast Stainless Steel Products for Medical Instruments

DIN 17 442

Walzwerks-, Schmiede- oder Gießerei-Fertigerzeugnisse aus nichtrostenden Stählen für medizinische Instrumente

1 Scope

1.1 This Standard contains a survey of the stainless steels available for use in manufacturing medical instruments (see Table 1) and of the as-delivered conditions and product forms in which they are normally supplied for the purposes mentioned (see Table 2). It is limited as far as possible to the essential information required for ordering these products and therefore applies only in combination with the quality standards listed in Table 1

DIN 17 440 Stainless steels; quality specifications

DIN 17 224 (Preliminary Standard) Stainless steel wire and strip for springs; quality specifications

and in conjunction with the dimension standards specified in Table 2.

In selecting grades of steel, shape and dimensions and the as-delivered condition of the raw product for manufacture of medical instruments, to some extent it is necessary to take into account aspects which, as for example the design of the instruments or the production facilities of the manufacturer, it is not possible to take into account adequately in a standard such as this. For this reason, it is not intended nor is it possible that the information given in this Standard should remove from the instrument manufacturer the decision-making responsibility for selecting an appropriate raw product with suitable properties. The standards for medical instruments listed in Section 1.2 must be observed in making this decision because these may contain additional or new information to be taken into account in selecting the steel.

1.2 For the finished instruments, the dimension standards for the instruments and the grouped requirements for instruments contained in the following parts of

DIN 58 298 Part 1 Medical instruments; forceps, materials, finish, testing

DIN 58 298 Part 2 Medical instruments; scissors, materials, finish, testing

DIN 58 298 Part 3 Medical instruments; forceps with bow handles, materials, finish, testing

DIN 58 298 Part 4 Materials, finish and testing of medical instruments; bone cutting forceps and rongeurs

DIN 58 298 Part 5 Materials, finish and testing of medical instruments; branch forceps

DIN 58 298 Part 6 Materials, finish and testing of medical instruments; conchotomes

DIN 58 298 Part 7 Materials, finish and testing of medical instruments; scalpels and knives

DIN 58 298 Part 8 Materials, finish and testing of medical instruments; retractors

DIN 58 298 Part 9 Materials, finish and testing of medical instruments; probes

DIN 58 298 Part 10 Materials, finish and testing of medical instruments; chisels and gouges, bone curettes

DIN 58 298 Part 15 Materials, finish and testing of medical instruments; dental explorers, filling and moulding instruments

DIN 58 298 Part 16 Materials, finish and testing of medical instruments; scalers

DIN 58 298 Part 17 Materials, finish and testing of medical instruments; extracting forceps

DIN 58 298 Part 18 Materials, finish and testing of medical instruments; elevators

apply.

N o t e : The information contained in this Standard on the use of the various grades of steel in the medical field is identical with the corresponding information in the relevant dimension standards and in DIN 58 298 Parts 1 to 18 apart from a few changes brought about by new developments (see Footnotes 4 and 6 in Table 1).

In addition the standard

DIN 17 443 Rolled and forged stainless steel products for surgical implants

covers a neighbouring field of application to the present standard (see Table 1, columns 26 and 27).

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2 Dimension standards

2.1 The principal dimension standards to be observed when ordering the rolled and wrought products covered by this Standard are listed in Table 2.

N o t e: At a later date, an attempt will be made to correlate the dimension standards on the basis of which the required raw products for manufacture of medical instruments are mainly ordered, directly with each individual medical instrument as has been done for implants in DIN 17 443. Any information to assist this would be welcome.

2.2 Because of the special features of stainless steels, the information contained in dimension standards not expressly relating to stainless steels cannot always be completely applied to such steels. Where applicable, the manufacturer should, when accepting the order, draw attention to any necessary departures of this kind from the dimension standard.

2.3 For precision castings, the dimensions and the permissible geometrical and dimensional variations should be agreed at the time of ordering.

3 Grades of steel, as-delivered conditions and product form and relevant quality standards

3.1 The grades of steel and as-delivered conditions for the raw products for manufacture of medical instruments are given in Table 1 and the principal forms of raw product used are shown in Table 2.

3.2 For ordering and supply of steels, the standards listed in column 4 of Table 1 apply. In those cases where the present Standard is specified in column 4 of Table 1, the information in Appendix A of this Standard applies for delivery.

4 Ordering

For ordering, the code number or the material number for the grade of steel and the information on the as-delivered condition and product form together with the number of the standard specified in Table 1, column 4 are to be appended to the designation obtained from the dimension standard for the product, as shown in the following examples:

1. Example

For hot rolled round steel bar of 10 mm diameter in manufacturing lengths according to DIN 1013 of steel X20Cr13 (material number 1.4021) in the soft annealed condition (G) in the hot rolled, heat treated, descaled (c1) product form:

Round 10 DIN 1013 – X 20 Cr 13 – hot rolled, soft annealed, descaled, DIN 17 440

or

Round 10 DIN 1013 – X 20 Cr 13 c1 (G) DIN 17 440

or

Round 10 DIN 1013 – 1.4021 – hot rolled, soft annealed, descaled DIN 17 440

or

Round 10 DIN 1013 – 1.4021 c1 (G) DIN 17 440

2. Example

For bright round steel bar of 10 mm diameter in manufacturing lengths according to DIN 668 of steel X 20 Cr 13 (material number 1.4021) in a condition strainhardened to a tensile strength of 650 to 850 N/mm^2 (K 65) in a mechanically or chemically descaled, cold formed, non-heat-treated product form (f):

Round 10 DIN 668 – X 20 Cr 13 – descaled, cold formed (K 65), not heat-treated DIN 17 442

or

Round 10 DIN 668 – X 20 Cr 13 f (K 65) DIN 17 442

or

Round 10 DIN 668 – 1.4021 – descaled, cold formed (K 65), not heat-treated DIN 17 442

or

Round 10 DIN 668 – 1.4021 f (K 65) DIN 17 442

Table 1. **Steels and as-delivered conditions for medical instruments including implantation instruments**

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Steel grade				Surgical instruments [1] DIN 58 298 Part											Accessories					Dental instruments [1] DIN 58 298 Part					Implantation instruments [1]					
					1	2	3	4	5	6	7	8	9	10							15	16	17	18								
	Code number	Material number	As-delivered condition [2]	DIN number [3]	Forceps	Scissors	Forceps with bow handles	Bone rongeurs	Bone cutting forceps	Branch forceps	Conchotomes	Scalpels and knives	Retractors	Probes	Chisels and gouges bone curettes	Springs	Handles, solid	Hollow handles	Guide pins	Screws, nuts	Dental explorers	Scalers	Extracting forceps	Elevators	Special dental forceps	Guide pins	Nail impactors, nail drivers	Extractors	Reamers and trochanteric reamers	Head for intramedullary canal reamer	Drill and nail gauge
	Martensitic steels																														
1	X 15 Cr13	1.4024	annealed	DIN 17440	×		×[6]				×		×	×			×		×	×	[4]			×	×	see DIN 17443	see DIN 17443				
2	X 20 Cr13	1.4021	annealed	DIN 17440	×		×	×	×	×	×		×	×	×	×	×	×	×	×			×		×			×	×		
3	X 20 Cr13	1.4021	K 65	DIN 17442 [5]		×		×	×	×	×	×			×						×			×	×			×	×	×	
4	X 40 Cr13	1.4034	annealed	DIN 17440		×		×	×		×	×			×						×	×		×	×				×		
5	X 38 CrMoV 15	1.4117	G	DIN 17442 [5]		×		×	×		×	×			×						×	[4]		×	×				×	×	
6	X 45 CrMoV 15	1.4116	annealed	DIN 17440		×[6]		×	×		×	×			×						×	[4]		×	×						
7	G-X 20 CrMo 13	1.4120	G	DIN 17442 [5]											×																
8	G-X 35 CrMo 17	1.4122	G	DIN 17442 [5]											×																
	Martensitic and austenitic automatic machine steels																														
9	X 12 CrMoS 17	1.4104	K 55	DIN 17440													×			×											
10	X 12 CrMoS 17	1.4104	K 65	DIN 17440													×		×	×											
11	X 12 CrNiS 18 8	1.4305	K 70	DIN 17440													×		×	×											
12	X 12 CrNiS 18 8	1.4305	quenched	DIN 17440										×	×		×			×											
	Austenitic steels																														
13	X 5 CrNi 18 9	1.4301	quenched	DIN 17440	×	×	×						×	×				×	×		×										
14	X 12 CrNi 17 7	1.4310	K	DIN 17224												×															×
15	X 5 CrNiMo 18 10	1.4401	quenched	DIN 17440	×	×	[4]																								

1) See Section 1.1 and Section 1.2.
2) N.B.: The normal condition of steel products when delivered to the instrument manufacturer. G = soft annealed, K = cold formed, KXX = cold formed to a tensile strength of XX · 10 N/mm².
3) Note: For titles of standards see Section 1.1.
4) Note: This grade of steel is still covered by the Part of DIN 58 298 specified above in the issue valid at the time of publication of this Standard.
5) N.B.: See Section 3.2 and Appendix A.
6) Note: This grade of steel is left unconsidered in the Part of DIN 58 298 specified above in the issue valid at the time of publication of this Standard.

Table 2. **Principal dimension standards, as-delivered conditions and product forms of raw products for manufacture of medical instruments**

Dimension standard		Relevant	
DIN number	Title	as-delivered conditions	product forms according to DIN 17440
Hot-formed rolled and forged products			
DIN 1016	Flat products of steel; hot rolled strip, hot rolled sheet under 3 mm thickness; dimensions, permissible variations on dimension, form and weight	G quenched	b, c 1, c 2 or e[2]
DIN 1017 Part 1	Steel bars; hot rolled flat steel for general purpose; dimensions, weights, permissible variations		
DIN 7527 Part 6	Steel forgings; machining allowances and permissible variations for open-die forged bars		
DIN 1013 Part 1	Steel bars; hot rolled round steel for general purpose; dimensions, weights, permissible variations on dimension and form		
DIN 1013 Part 2	Steel bars; hot rolled round steel for special purpose; dimensions, permissible variations on dimension and form		
DIN 59130	Hot rolled round steel bars for bolts and rivets; dimensions, weights, permissible variations		
DIN 59110	Steel wire rod; dimensions, permissible variations, weights		
DIN 59115	Steel wire rod for bolts, nuts and rivets; dimensions, permissible variations, weights		
Cold rolled or cold-drawn products			
DIN 59381	Flat products of steel; cold rolled steel strip of stainless or heat resisting steels; dimensions, permissible variations on dimensions, form and weight	G quenched K 55 K 65 K 70 K	h, m[3], n, o[4] or p[4]
DIN 59382	Flat products of steel; cold rolled wide mill strip and sheet of stainless steels; dimensions, permissible variations on dimensions and form		h, m[3], n, o[4] or p[4]
DIN 174	Bright flat steel; dimensions, permissible variations, weights		f, o[4] or p[4]
DIN 175	Polished round steel; dimensions, permissible variations according to ISA tolerance zone h9, weights		
DIN 668	Bright round steel; dimensions, permissible variations according to ISA tolerance zone h11, weights		
DIN 671	Bright round steel; dimensions, permissible variations according to ISA tolerance zone h9, weights		
DIN 176	Bright drawn hexagon steel; dimensions, permissible variations, weights		
DIN 2076	Round spring wire; dimensions, weights, permissible variations		
DIN 4186 Part 1	Screening surfaces; round metal wires; dimensions		

1) Table 1 shows the steels to which the various as-delivered conditions apply.
2) Only for bar steel.
3) Not for bar steel.
4) Only for bar steel over about 2 mm diameter in conjunction with the appropriate dimension standards.

Appendix A

Provisional conditions of delivery for the grades of steel or as-delivered conditions [1] which can be ordered in accordance with Table 1, column 4 of the present Standard but have not so far been otherwise standardized

Grade of steel			Chemical composition in % by wt. (ladle analysis)								Mechanical properties [3]				Other technical conditions of delivery
Code number	Material number	As-delivered condition [2]	C	Si	Mn	P maximum	S maximum	Cr	Mo	Others	for diameter d or thickness e mm	$R_{p0,2}$ mind. N/mm²	R_m N/mm²	A_5 mind. %	
X20 Cr 13	1.4021	K 65	0.17 to 0.22	≦ 1.0	≦ 1.0	0.045	0.030	12.0 to 14.0	–	–	$d \leqq 40$ $e \leqq 30$	500	650 to 850	10	DIN 17 440
X38 CrMoV15	1.4117	G	0.35 to 0.40	≦ 1.0	≦ 1.0	0.045	0.030	14.0 to 15.0	0.40 to 0.60	V : 0.10 to 0.15	$d \leqq 40$ $e \leqq 5$		≦ 900		[4]
G-X 20 CrMo 13	1.4120	G	0.17 to 0.22	≦ 1.0	≦ 1.0	0.045	0.030	12.0 to 14.0	0.9 to 1.3	Ni: ≦ 1,0	$d \leqq 40$ $e \leqq 5$		≦ 800		[4]
G-X 35 CrMo 17	1.4122	G	0.33 to 0.43	≦ 1.0	≦ 1.0	0.045	0.030	15.5 to 17.5	0.9 to 1.3	Ni: ≦ 1,0	$d \leqq 40$ $e \leqq 5$		≦ 950		[4]

1) Note: It is intended to include complete conditions of delivery for these grades of steel or as-delivered conditions in delivery standards or iron and steel delivery specifications and hence ultimately replace the information given in this Appendix A.

2) N.B.: K 65 = cold-formed to a tensile strength of ≧ 650 N/mm², G = soft annealed.

3) Note: $R_{p\,0.2}$ = 0.2% proof stress, R_m = ultimate tensile strength, A_5 = elongation for $L_0 = 5\,d_0$.

4) Note: Where necessary, further conditions of delivery should be agreed for this at the time of ordering, where possible on the basis of relevant existing standards.

Explanations

The standardization work on medical instruments has been substantially increased in extent so that it appeared desirable to bring together in a standard the steels that can be used in this field.

Steels for implants, which were still contained in the draft of DIN 17 442, have been brought into a standard of their own (DIN 17 443) to provide better harmonization with the relevant ISO standard (DIS 5832/1).

This Standard is essentially limited to providing the information necessary for ordering and otherwise refers to the dimension standards and quality standards applicable to the products, mentioned in Table 1 or Table 2, so that such standards constitute an essential part of this Standard. The basic documents for selecting grades of steel are the various Parts of DIN 58 298 already mentioned and the steel applications list 430, "Stainless steels and alloys for medical purposes", of the Verein Deutscher Eisenhüttenleute (German Welding Association).

Compared with the draft standard, in the final version of this Standard, the precision cast grades G-X 20 CrMo 13 (material number 1.4120) and G-X 35 CrMo 17 (material number 1.4122) have been additionally included and grade X5 CrNi 1911 (material number 1.4303) deleted. The new adoption of precision cast grades resulted from the additional inclusion of further instruments. Chisels, gouges and bone curettes and also elevators and probes have been added.