

Declaration of Quality

For our high-quality instruments we use only German Steel conforming to DIN 58298:2010-09 "Medical instruments-Materials, finish and testing", DIN EN ISO 13402 and EN ISO 7153-1:2002 "Surgical instruments - Metallic materials - Part 1: Stainless steel", whereby we fulfil even higher requirements than those stipulated in the standards by our own delimitation of the analysis values and the permissible structural condition.

By doing this, we improve the mechanical properties and the corrosion resistance of our instruments.

In our own material testing laboratory, equipped with the most modern testing equipment (chemical analysis, scanning electronic microscope, autoclave-test etc) we test and monitor every batch of raw material we receive, thus ensuring that only absolutely perfect material is employed in our production. We also guarantee a 100% traceability of each charge of raw material in case of any complains.

In detail we use the following materials in production:

Instrument	ISO Norm	Material acc. to German Industrial norm	Values in % acc. to Analyses	Hardness acc. to Rockwell Standards	USA Type AISI
All kind of Forceps, Needle Holders, Wound Retractors, Pliers	1.4021	X 20 Cr 13	C: 0,16-0,25 Cr: 12,0-14,0 Si: max. 1,0 Mn: max 1,5 S: max 0,015 P: max. 0,040	44-48	420
All kind of Scissors	1.4116	X 50 CrMoV 15	C: 0,45-0,55 Cr: 14,0-15,0 Mo: 0,50-0,80 V: 0,10-0,20 Si: max. 1,0 Mn: max. 1,0 S: max. 0,015 P: max. 0,040	52-58	-----
	1.4117	X38 CrMoV15	C: 0,35-0,40 Cr: 14,0-15,0 Mo: 0,40-0,60 V: 0,10-0,15 Si: max. 1,0 Mn: max. 1,0 S: max. 0,030 P: max. 0,045		
Raspatories, Chisels sharp, Dental Instruments, Roungeurs, Scalpel Handles	1.4034	X 46 CR 13	C: 0,43-0,50 Cr: 12,5-14,5 Si: max. 1,0 Mn: max 1,0 S: max. 0,015 P: max. 0,040	50-58	420C
Depressors, Vaginal Speculums, Maleable Instruments	1.4301	X 5 Cr Ni 18 10	Cr : 17,5-19,0 Ni : 8,0-10,5 C: max 0,07 Si: max 1,00 Mn: max 2,00 P: max 0,045 S: max 0,015	5-20	304

All instruments are passivated and all instruments are hardening and both process are validated.

All our instruments are UDI laser-marked according to the GS1 standard (supplier, item number, LOT number and Data matrix) and CE.

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