

## Declaration of Quality

For our high-quality instruments we use only German Steel conforming to DIN 96298-1:2016-10, DIN 96298-2:2016-10, DIN 96298-3:2017-10 "Medical instrument – Terms, measuring methods and tests", DIN EN ISO 13402:2001-02, DIN EN ISO 7153-1:2017-02, ISO 7151, ISO 7741, ISO 5194-2, ASTM F899, ASTM A380-06 and ASTM A967 / A967M -17. Whereby we fulfill 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 norms DIN EN 10088-1:2014-12 DIN EN 10088-2:2014-12 DIN EN 10088-3:2014-12	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	Tungsten carbide jaws 60-64 42-50	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	50-58	-----
	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
	1.4305				

All our instruments are laser-marked, passivated and hardened in protective atmosphere, all this processes are validated. The passivation is performed with citric acid at 65 degrees 8min.

All our instruments are UDI marked according to the GS1 standard (supplier, item number, unique serial number in Data matrix) and CE.

Tuttlingen, 26.09.2024



Thomas Butsch,  
CEO, HEBUmedical GmbH, Germany