



unimed

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## INFORMATION SHEET

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<b>MATERIAL</b>	AISI 316L	<b>FAMILY</b>	Austenitic stainless steel	<b>SHEET #</b>	AISI316L.FIE
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EQUIVALENCY				
DIN	AFNOR	UNS	SS	ISO
1.4404 (X2CrNiMo17-12-2)	Z2 CND 17-12/13	S31603	2348 / 2353	4404-316-03-I
1.4435 (X2CrNiMo18-14-3)				4435-316-91-I

USE			
This material is commonly used for the manufacture of the following product elements:			
<input checked="" type="checkbox"/> Cannula (tube)	<input checked="" type="checkbox"/> Stylet (wire)	<input checked="" type="checkbox"/> Hub	<input checked="" type="checkbox"/> Handle
<input checked="" type="checkbox"/> Adaptor	<input checked="" type="checkbox"/> Stopcock		

GENERAL CHARACTERISTICS		
<b>Straightness</b>	<b>Circularity</b>	<b>Concentricity</b> (only tube)
2 mm difference for 1'000 mm length	- Tube :           Circularity $\cong$ ID tolerance - Wire:           Circularity $\cong$ OD tolerance	$\leq$ 10% tube thickness
<b>Outer surface finish</b>	<b>Inner surface finish</b> (only tube)	-
N5 ( $R_{a\max} = 0.4$ )	N7 ( $R_{a\max} = 1.6$ )	-

MANUFACTURING			
<b>Turing, drilling, milling</b>	<b>Grinding</b>	<b>Laser cutting</b>	<b>Electro erosion machining</b>
Not suggested	Good	Excellent	Good
<b>Sharpening</b>	<b>Polishing</b>	<b>Laser marking</b>	-
Excellent	Good	Excellent	-

ASSEMBLING			
<b>Bonding</b>	<b>Press fit</b>	<b>Soldering</b>	<b>Laser welding / Plasma</b>
Good	Not suggested	Good	Excellent

CHEMICAL COMPOSITION [%]									
C	Si	Mn	P	S	Cr	Ni	Mo	N	-
$\leq 0.03$	$\leq 1.0$	$\leq 2.0$	$\leq 0.045$	$\leq 0.03$	16-18	10-14	2-3	$\leq 0.1$	-

The reference to the chemical composition is the one from UNS.

The chemical composition from other equivalent standards may be slightly different from that provided in this information sheet.

MECHANICAL PROPRIETIES	
Material state	Tensile strength Rm [MPa]
Hard – Cannula	800 – 1'500
Annealed – Cannula	400 – 700
Hard – Stylet	1'400 – 2'400

PHYSICAL PROPRIETIES		
Density $\rho$ [kg/m <sup>3</sup> ]	Electrical resistivity $\rho$ [ $\mu\Omega \times m$ ]	Thermal conductivity $\lambda$ [W/(m $\times$ K)] at 20°C
7'980	0.75	15
Modulus of elasticity E [GPa] at 20°C	Coefficient of linear thermal expansion $\alpha$ [ $10^{-6} / ^\circ C$ ] between 20°C and 100°C	Specific heat capacity C <sub>p</sub> [J/(kg $\times$ K)] at 20°C
200	16.5	500

Corrosion resistance
Excellent corrosion resistance

BIOCOMPATIBILITY (ISO 10993-1)
The austenitic stainless steel AISI 316L is a metallic material derived from AISI 316 stainless steel, material referenced in the American standard of surgical instruments ASTM F899, considered as clinically established and recognized material (state-of-the-art) for devices medical. It may require justifications and/or specific biocompatibility tests. The stainless steel AISI 316L is however referenced in the standard ISO 16061.
Their needs can be determined in a biological safety analysis of specific medical device. The customer is responsible to verify the compatibility of the material selected from its intended use.

STANDARDS	
ISO 15510	Stainless steels -Chemical composition
ISO 9626	Stainless steel needle tubing for the manufacture of medical devices
ISO 7153-1	Surgical instruments - Metallic materials - Part 1: Stainless steel
ASTM F899	Standard Specification for Wrought Stainless Steels for Surgical Instruments
ISO 16061	Instrumentation for use in association with non-active surgical implants - General requirements

All this information are for reference only. They have no legal or contractual commitment Unimed SA.

04.08.2022	Page 1/1
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