

## Medical applications

Opt for a stainless steel health



**Swiss  
Steel**  
Group





# Ugitech: your partner for stainless steel health

**Ugitech produces stainless steels and alloys in the form of bar and wire rod: raw materials for your medical devices and equipment.**

Ugitech stands out for its internationally-recognised technical culture and expertise in producing long stainless steel products.

Ugitech ensures its customers a completely integrated manufacturing which allows a total control of the quality, from the liquid metal to the product delivered to the customer. Ugitech is ISO 13485-certified.

Thanks to its cutting-edge research and development centre, Ugitech is able not only to develop new alloys but also to provide technical expertise (product co-development and technical support in transformation) for the manufacture of your devices.

In order to best meet the requirements of the medical market, Ugitech has structured itself into four main areas with an adapted product offer:

- External equipment (dialysis system, artificial respirator, imaging...)
- Implantable Medical Devices: orthopaedic, traumatological, vascular implants.
- Medical Devices: Instruments and tools (surgery, orthopaedic instruments, endoscopy...)
- Dental (equipment, cutters, tools...)

Ugitech, Swiss Steel Group, benefits from an experienced worldwide commercial presence thanks to its international sales network.

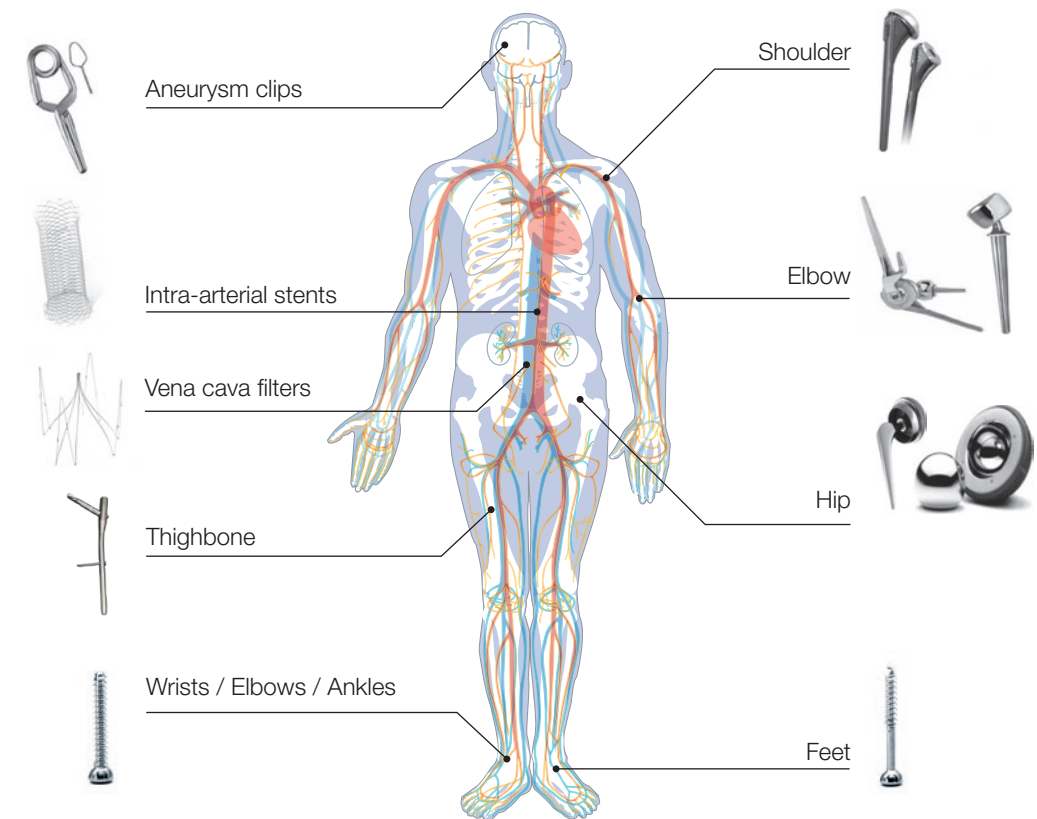


Surgery and endoscopy instruments



Scanners

## Implantable Medical Devices (IMD)



### Stainless steel grades for orthopaedic, traumatological and vascular implants

Ugitech designation	EN / AISI designation	Standard	Surface finishes	Products
UGI® 4441	EN 1.4441 DIN 17443 AISI 316LVM UNS S31673	ISO 5832-1 ASTM F138	Annealed	Bars and wire
			Cold worked	Bars and wire
			Extra-hard	Bars
UGI® 4472*	EN 1.4472 UNS S31675	ISO 5832-9 ASTM F1586	Annealed	Bars and wire
			Medium hard	Bars
			Hard	Bars
			Cold drawn	Wire

Other states of work-hardening according to customer specifications are available on request.

\* Sizes for sale ≤ 18 mm

### Cobalt-based alloy grades for orthopaedic, traumatological and vascular implants

Ugitech designation	EN / AISI designation	Standard	Surface finishes	Products
UGIALLOY® PHYNOX®	EN 2.4711 UNS R30003 UNS R30008	ISO 5832-7 ASTM F1058	Annealed	Bars and wire
			Cold worked	
UGIALLOY® KC35N	EN 2.4999 UNS R 30035	ISO 5832-6 ASTM F562	Annealed	Bars and wire
			Cold worked	
UGIALLOY® HT605	EN 2.4964 UNS R30605	ISO 5832-5 ASTM F90	Annealed	Bars and wire
			Cold worked	

Other hardening conditions according to customer specifications are available on request.

Products available in max. 14mm diameter.

PHYNOX® is a registered trademark of Aperam.

# Medical devices (MD)

Ugitech designation	EN designation	AISI designation	Low sulfur grade	MDR 2017/745 involves LR grade (Co < 0,1%)	UGIMA®	Forgeability (improved)	Remelting process	ASTM F899	ISO 7153	EN 10088-3	NF S94-090	ASTM	ISO
UGI® 4005	1.4005	416	-		option	-	-	■	■				
UGI® 4006	1.4006	410	option		option	yes	-	■	■	■			
UGI® 4016	1.4016	430	option			yes	-	■	■	■			
UGI® 4021	1.4021	420A	option	option LR	option	(option)	-	■	■	■	■		
UGI® 4028	1.4028	420B	option	option LR	option	(option)	-	■	■	■	■		
UGI® 4031	1.4031	420C			-	yes	-	■		■			
UGI® 4034	1.4034	420C	option	option LR	-	yes	-	■	■	■	■		
UGI® 4035	1.4035	420F	-	option LR	-		-	■		■			
UGI® 4037	1.4037		yes		-	yes	-		■				
UGI® 4197	1.4197/1.4121	420F MOD	-	option LR	-		-	■	■	■			
UGI® 4122	1.4122	-	-		-	yes	-		■	■			
UGI® 4116N	1.4116	-	option	on request	option	(option)	-		■	■			
UGI® 4057	1.4057	431	option	option LR	option	(option)	option	■	■	■	■		
UGI® 4542	1.4542	630 (17-4PH)	option	option LR	option	yes	option	■	■	■	■		
UGI® 4104	1.4104	430F	-	option LR	option		-			■			
UGI® 4105	1.4105	430F	-				-	■	■	■			
UGI® 4305	1.4305	303	-	option LR	option		-	■	■	■			
UGI® 4307	1.4307	304L	option	option LR	option	(option)	option	■	■	■	■		
UGI® 4310	1.4310	302/304H	yes	on request	-	yes	-	■	■	■	■		
UGI® 4404	1.4404	316L	option	option LR	option	(option)	option	■	■	■	■		
UGI® 4435	1.4435	316LMO	option		option	(option)	option			■	■		
UGIPURE® 4441	1.4441	316LVM	yes	yes	-	yes	yes	■	■	■	■	F138	5832-1
UGIPURE® 4472	1.4472	UNS 31675	yes	yes	-	yes	yes					■	F1586 5832-9
UGI® 4568	1.4568	631 (17-7PH)	yes		-		-	■		■			
UGIMA® 4598	1.4598	316LCu	-		option		-			■			
UGIALLOY® PHYNOX®	2.4711	R30003/30008		Alloys Co			yes					F1058	5832-7
UGIALLOY® KC35N	2.4999	R300035		Alloys Co			yes					F562	5832-6
UGIALLOY® HT605	2.4964	R30605		Alloys Co			yes					F90	5832-5

N.B.: UGIMA® is a special process to improve machinability. PHYNOX® is a registered trademark of Aperam. Ugitech supplies products whose chemical, mechanical and metallographic properties are in compliance with the standards and regulations required and used by medical device (MD) manufacturers. Medical device manufacturers are responsible for verifying, ensure and control the safety and biocompatibility of the medical device, particularly those at the patient-device interface.

### Technical recommendations

- Low Sulfur grades: adapted for invasive instruments, part with thin walls, part for endoscopy, small diameter products, parts subjected to fatigue stress...
- Remelting Process: critical MD; subjected to fatigue stress, and long lasting contact with tissues.

Ugitech designation	EN designation	AISI designation	Corrosion resistance (low sulphur grade)	Hardness (treated condition)	Hardening process	Tensile Strength (After HT / SH)	Machinability (UGIMA® when available)
UGI® 4005	1.4005	416	■	■	HT	■	■
UGI® 4006	1.4006	410	■	■	HT	■	■
UGI® 4016	1.4016	430	■	N.A.	N.A.	■	■
UGI® 4021	1.4021	420A	■	■	HT	■	■
UGI® 4028	1.4028	420B	■	■	HT	■	■
UGI® 4031	1.4031	420C	■	■	HT	■	■
UGI® 4034	1.4034	420C	■	■	HT	■	■
UGI® 4035	1.4035	420F	■	■	HT	■	■
UGI® 4037	1.4037		■	■	HT	N.A.	■
UGI® 4197	1.4197/1.4121	420F MOD	■	■	HT	N.A.	■
UGI® 4122	1.4122	-	■	■	HT	■	■
UGI® 4116N	1.4116	-	■	■	HT	N.A.	■
UGI® 4057	1.4057	431	■	■	HT	■	■
UGI® 4542	1.4542	630 (17-4PH)	■	Acc. to condition	HT (PH)	■	■
UGI® 4104	1.4104	430F	■	■	HT	■	■
UGI® 4105	1.4105	430F	■	N.A.	N.A.	■	■
UGI® 4305	1.4305	303	■	N.A.	SH	■	■
UGI® 4307	1.4307	304L	■	N.A.	SH	■	■
UGI® 4310	1.4310	302/304H	■	N.A.	SH	■	■
UGI® 4404	1.4404	316L	■	N.A.	SH	■	■
UGI® 4435	1.4435	316LMO	■	N.A.	SH	■	■
UGIPURE® 4441	1.4441	316LVM	■	N.A.	SH	■	■
UGIPURE® 4472	1.4472	UNS 31675	■	N.A.	SH	■	■
UGI® 4568	1.4568	631 (17-7PH)	■	N.A.	HT (PH) & SH	■	■
UGIMA® 4598	1.4598	316LCu	■	N.A.	SH	■	■
UGIALLOY® PHYNOX®	2.4711	R30003/30008	■	■	HT	■	■
UGIALLOY® KC35N	2.4999	R300035	■	■	HT	■	■
UGIALLOY® HT605	2.4964	R30605	■	■	SH	■	■

HT: Heat Treatment to harden  
SH: Strain Hardening  
PH: Precipitation Hardening

Our products comply with standards in force for the manufacturing of the medical devices specifically in terms of metallurgical properties. However, Ugitech did not and will not perform any bio compatibility tests even for medical applications. It is the responsibility of the designer / manufacturer of the medical device to ensure such bio compatibility and medical fitness of the chosen steel.

# Size ranges and services

## Round bars

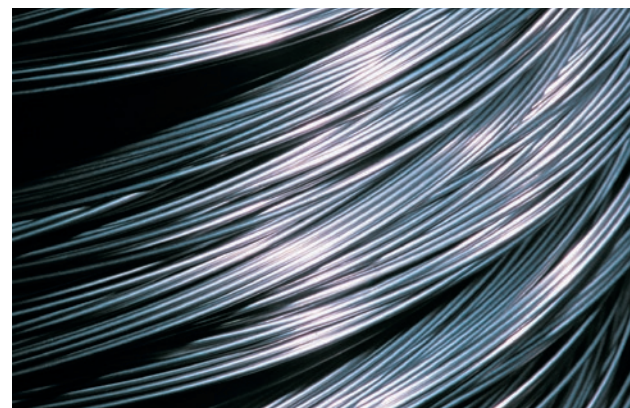
	Size range	Surface finishes	Tolerances
Ex-mill	$1.6 \leq \varnothing < 20$	Turned and polished/ground	h6, h7, h8, h9
	$20 \leq \varnothing \leq 130$		h9, h10
Ex-stock	$1.8 \leq \varnothing < 20$	Turned and polished/ground	h8, h9
	$20 \leq \varnothing \leq 130$		h9, h10

## Drawn wires

	Size range	Surface finishes	Tolerances	Packaging
Round wire	1-15mm	Matt	Up to ISO 6 according to application	Coils and carriers
Shaped wire	2 to 70mm <sup>2</sup>	Bright finished	To within 0.1mm	Coils

### Additional services:

- Sawing, cutting to length
- Special end finishing on demand
- Heat treatment (hardening or stress-relieving)
- Specific non-destructive testing
- Marking (laser, hard stamping, ink) on section or on line marking
- Packaging for bars:
  - Fumigated wooden crates for all precision-ground products (on request for other surface quality).
  - Strapping with "akilux" alveolar polypropylene fabric.
- Customer-dedicated stock items
- Customisation and tailored products according to customer requirements (mechanical properties, marking, length, machinability, cleanness, etc.)
- Delivery plan management



# Quality management dedicated to the medical market

## System Quality

In order to take into account the requirements of this market, Ugitech integrated in 2015 in its quality management system that of the medical devices industry (ISO 13485 certification for Ugitech production facility and Grigny service center).

## Product Quality

Ugitech is ISO 17025 certified in a range of areas from chemical analysis to mechanical testing, including metallographic and non-destructive testing.

Ugitech also works with external partner laboratories, all ISO 17025 certified.

Ugitech is equipped with the latest non-destructive testing technologies (Eddy current, ultra sound).

## Certified inspection possibilities as per ISO 17025

Nature of test or analysis	Measured characteristic	Method reference
Physical-chemical analysis	Chemical analysis	X-ray fluorescence, spectrometry, combustion and infrared absorption
Grain size determination	Grain size index	NF EN ISO 643, ASTM E112
Determination of non-metallic inclusion content	Inclusion content	ISO 4967, ASTM E45
Detection of metallurgical defects by chemical attack	Micrographic observation	ASTM A604/604M
Determination of delta ferrite	Delta ferrite content	AMS 2315
Mechanical specifications: Traction test	Rp0.2; Rm; A %; Z	ISO 6992-1, ASTM E8/E8M
Mechanical specifications: Hardness test	HRC, HB, HV	ISO 6506-1, ISO 6507-1, ISO 6508-1

## Compliance and order release for implantable products (IMD)

On each bar intended for the manufacturing of implantable products (IMD), Ugitech imposes an FX spectrometer control and a continuous marking on the generator (line marking). A final control before shipment is carried out by our quality inspectors.

## Traceability and archiving

Ugitech guarantees its customers complete traceability from the liquid metal to the delivered product.

Ugitech uses IT resources (SAP, GED) enabling it to undertake document archiving that extends beyond the service life of the medical devices.

Material certificates are available via a web portal (eServices) and are accessible at any time.



**Swiss Steel Group**

[medical@swisssteelgroup.com](mailto:medical@swisssteelgroup.com)

[www.swisssteel-group.com](http://www.swisssteel-group.com)

The information and data presented here in are typical or average values and are not a guarantee of maximum or minimum values. Only the information reported on our material certificates is to be considered as relevant.

Applications specifically suggested for material described herein are made for the purpose of illustration only to enable the reader to make its own evaluation and are not intended as warranties, either express or implied, of fitness for any purposes.