CERTIFICATE

Number: 2194636

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Assut Medical Sàrl

Avenue de Rochettaz 57 **1009 Pullv** Switzerland

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design, manufacturing and distribution of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Certificate expiry date: Certificate effective date: 22 February 2020 Certified since:

22 February 2023 20 September 2016

This certificate is valid for the organization(s) and/or/locations mentioned on/the addendum

DEKRA Certification B.V.

B.T.M. Holtus Managing Director filligt

J.A. van Vugt Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

To certificate: 2194636

The management system of the organization(s) and/or location(s) of:

Assut Medical Sàrl

Avenue de Rochettaz 57 1009 Pully Switzerland

Certified additional organization(s) and/or locations:

Organization/Location

Assut Medical Sàrl

Sur le Crêt 13 2606 Corgemont Switzerland

Scope:

DEKRA

Design and manufacturing of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Assut Medical Sàrl

Av. De Lavaux 35 P.O. Box 5 CH-1009 Pully / Lausanne Switzerland

Scope:

Design and distribution of sterile surgical sutures, pacing wires, micro-surgical knives and non-sterile atraumatic needles for the area of surgery

Addendum expiry date: Addendum effective date: 22 February 2023 22 February 2020

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

EC CERTIFICATE

Number: 2194636CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4) (Devices in Class IIa, IIb or III)

Manufacturer:

Assut Medical Sarl Avenue de Rochettaz 57 1009 Pully Switzerland

For the product category(ies)

Non-absorbable surgical sutures

DEKRA grants the right to use the EC Notified Body Identification Number Illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2194636CN, initially dated 20 September 2016 Addendum, initially dated 23 September 2016

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for/ design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the guality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 12 December 2022 Issued for the first time: Reissued:

23 September 2016 12 December 2017

DEKRA Certification B.V.

B.T.M. Holtus Managing Director

filligt

J.A. van Vugt Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

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ADDENDUM

Belonging to certificate: 2194636CE01

CE MARKING OF CONFORMITY MEDICAL DEVICES

Non-absorbable surgical sutures

Issued to:

Assut Medical Sàrl

Avenue de Rochettaz 57 1009 Pully Switzerland

This certificate covers the following product(s):

- Astralen (Polyester) with or without pledgets Class III
- Nylon (Polyamide) Class III
- Polypropylene Class III
- Silk Class III
- PTFE Pledgets Class III
- Supramid (Polyamide) Class Ila
- Surgical Steel Class Ilb
- Astralen/Polyester Tape Class IIb
- AssuTopFiber® (UHMWPE) Class IIb, Rule 8

Initial date: 23 September 2016 Revision date: 4 April 2019

DEKRA Certification B.V.

B.T.M. Holtus Managing Director

Aubust

J.A. van Vugt Certification Manager

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EC CERTIFICATE

Number: 2194636CE03

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4) (Devices in Class IIa, IIb or III)

Manufacturer:

Assut Medical Sarl Avenue de Rochettaz 57 1009 Pully Switzerland

For the product category(ies)

Absorbable surgical sutures

DEKRA grants the right to use the EC Notified Body Identification Number Illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 2194636CN, initially dated 20 September 2016 Addendum, initially dated 23 September 2016

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 12 December 2022 Issued for the first time: Reissued:

23 September 2016 12 December 2017

DEKRA Certification B.V.

B.T.M. Holtus Managing Director

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J.A. van Vugt Certification Manager

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ADDENDUM

Belonging to certificate: 2194636CE03

CE MARKING OF CONFORMITY MEDICAL DEVICES

Absorbable surgical sutures

Issued to:

Assut Medical Sàrl

Avenue de Rochettaz 57 1009 Pully Switzerland

This certificate covers the following product(s):

- AssuCryl® MonoSlow (PDO)
- AssuCryl® Lactin (PGLA)
- AssuCryl® (PGA)
- AssuCryl® Rapid (PGA)
- AssuCryl® MonoRapid (PGCL)

Initial date: 23 September 2016 Revision date: 4 April 2019

DEKRA Certification B.V.

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Hilligh

J.A. van Vugt Certification Manager

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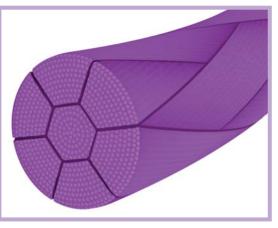
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of Switzerland

AssuCryl® synthetic absorbable







www.assutsutures.com



Introduction

Assut Medical Sàrl, with factory located since 1962 in the famous Swiss region of the watch-industry and fine metal technology, is specialized in the manufacturing of atraumatic surgical needles and sterile surgical sutures.

Constantly adapting and enlarging its range of products to meet modern surgery requirements, Assut sutures are designed and made for all surgical specialties and renown world-wide. Assut sutures meet the surgeon's requirements in all surgical procedures.

With a long history providing surgical sutures of the highest quality, you can count on a team of dedicated Personnel, Technicians and Specialists.

The way our products are shown and described hereafter will make it easy for you to choose and order your sutures. Our company is EN ISO 9001/EN ISO 13485 certified. Our production and products are in compliance with the requirements according to the European medical device directive 93/42/EEC and all our sutures are CE-marked.

Assut Medical Sàrl

AT THE SERVICE OF SURGERY

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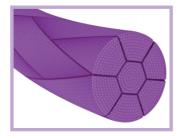




Assut sutures of Switzerland	CE 0344	REF 42454
AssuCryl® Absorbable (PGA	braided violet o	coated
	Metric (EP) 75 c	
	1 ~ 25°C () ∧	
2023-04 804024	STERIL	E EO 1/2c. R.B 25 mm

Suture Materials and Colour Codes —

Absorbable



AssuCryl®

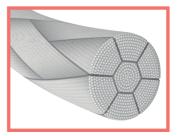
synthetic absorbable Braided, coated synthetic absorbable PGA. Predictable absorption time. High initial tensile strength. Easy and secure knotting. Excellent knot sliding and smooth to handle. Violet and undyed (white). Absorption essentially complete between 60 and 90 days.

AssuCryl® Rapid synthetic absorbable

Braided, coated synthetic absorbable PGA. Predictable shorter absorption time. High initial Predictable shorter absorption time, high initial tensile strength. Easy and secure knotting with excellent knot sliding, smooth to handle. Undyed (white) only. Absortion essentially complete between 40 to 45 days.

AssuCryl® MonoSlow

Monofilament synthetic absorbable PDO (Polydioxanone), violet. High initial tensile strength, easy to handle and smooth passage through tissue. Absortion essentially complete between 180 to 210 days.





AssuCryl® Lactin

synthetic absorbable Braided, coated synthetic absorbable PGLA. Predictable absorption time. High initial tensile strength. Easy and secure knotting. Excellent knot sliding and smooth to handle. Violet and undyed (white). Absorption essentially complete between 56 and 70 days.

AssuCryl[®] MonoRapid synthetic absorbable

Monofilament synthetic absorbable PGCL (Poliglecaprone). Available in violet or undyed. Easy to handle and smooth passage through tissue. Absorption essentially complete between 90 to 120 days.

synthetic absorbable





Non - Absorbable

Polyester coated/Astralen

Green braided polyester with improved tensile strength and knot security, siliconized. A modern braiding technique gives the strand a smooth and uniform surface that minimizes the trauma

Polypropylene

Blue monofilament polypropylene is flexible and ties securely. Extremely well tolerated, its smooth and uniform surface allows easy passage through tissue with minimum trauma





Silk

Black braided surgical silk on twisted core for greater tensile strength. Wax treatment and new braiding technique render the silk uniform and smooth and facilitate its handling.

Supramid

Black monofilament polyamide with supersoft core, resulting in superior pliability and knot security. The uniform and smooth surface permits effortless passage through tissue with minimum trauma. Supramid is extre-mely well tolerated.



Monofil Nylon/Polyamide

Blue monofilament polyamide with high tensile strength. The uniform and smooth surface permits effortless passage through tissue with minimum trauma. Extremely well tolerated.

Surgical Steel

Monofilament stainless steel with very high tensible strength and excellent knot security. This strand causes minimum tissue reaction.



——Information on Labelling —				
Symbol	Meaning			
2	Do not re-use. Disposable product			
	Expiry-date. Use until year/month			
LOT	Lot Number			
STERILE E0	Sterilized with Ethylene Oxide			
STERILE R	Sterilized with Gamma-Irradiation			
<u>_</u>	See instructions for use			
(E xxxx	CE Mark of the Notified Body			
REF	Product Number			
	Maximum Temperature °C			
	Do not use if packaging is damaged			
STERVIZE	Do not re-sterilize			

Information on REF

Each Assut product has a REF (Prod.No.) with either 3, 4 or more digits. The prefix or suffix letter(s), if any, refer to the suture material, such as:

Prefix

- M Monofilament
- R Rapid
- S Slow
- B Reel
- L Lactin

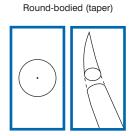
Suffix

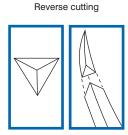
ΤН	30 cm long strand
THF	35 cm long strand
TE	38 cm long strand
F	45 cm long strand
S	60 cm long strand
	75 cm long strand
Ε	80 cm long strand
Ν	90 cm long strand
Η	100 cm long strand
HT	120 cm long strand
HF	150 cm long strand
HE	180 cm long strand
Т	200 cm long strand
TF	240 cm long strand
W	White (or undyed)

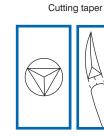
Needle shape and cross-section

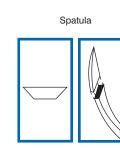
Logical needle codes

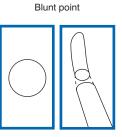
The shape, cross-section and length of needles are given by the needle codes, for example TS 60. The first letter refers to the shape of the needle, the second to the cross-section. The number stands for the needle length along the body (mm).









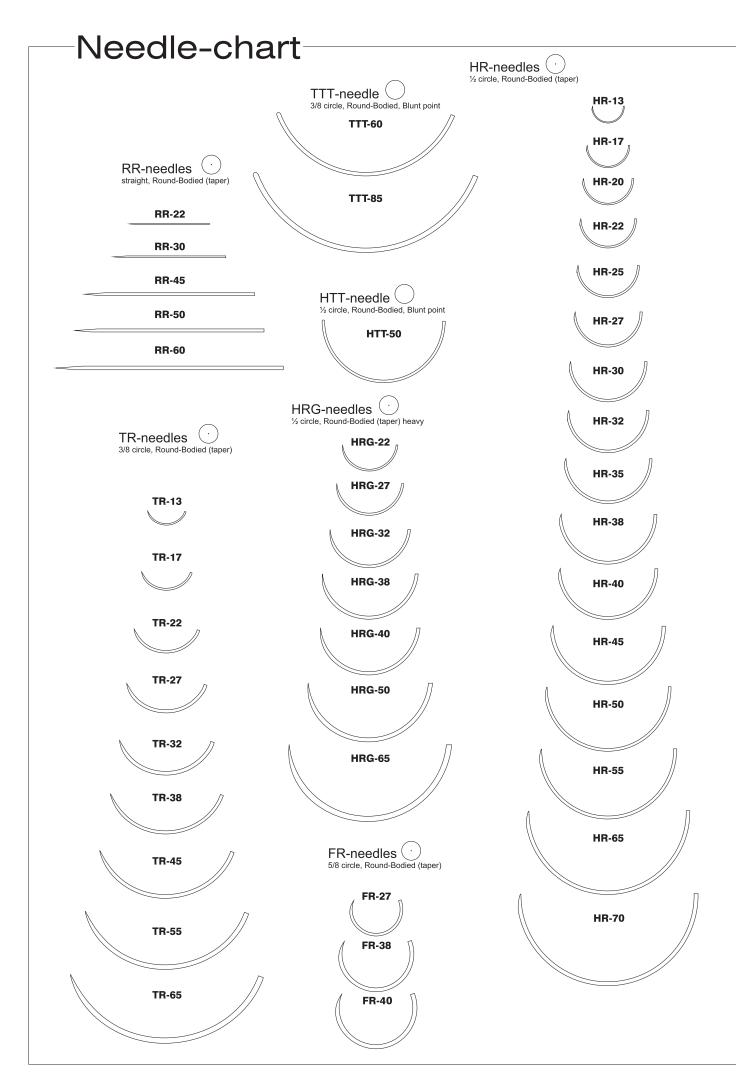


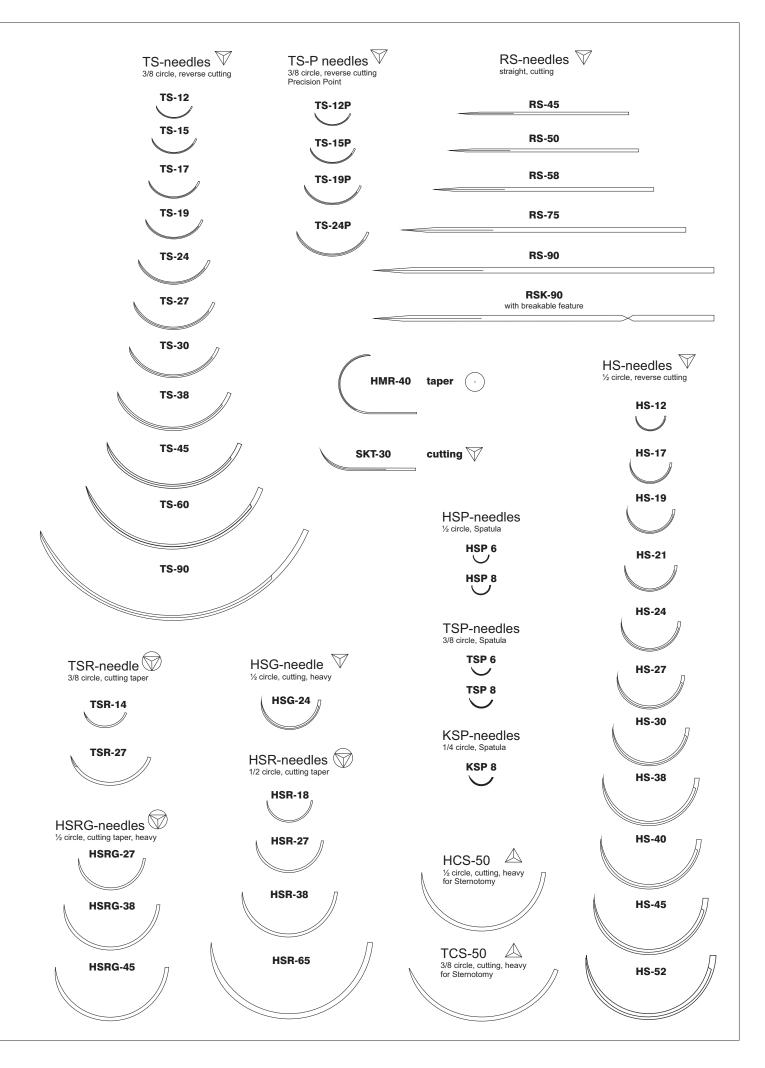
TS 60

3/8 circle reverse cutting, 60 mm

60 mm

Needle Code	Ne	edle Shape	edle Shape Cross-section		Symbol		
HR	н	1/2 circle	R	Round-Bodied (taper)			\odot
HRG	H	1/2 circle	R	Round-Bodied (taper)	G	heavy	\odot
HRM	H	1/2 circle	R	Round-Bodied (taper)	Μ	Micropoint	\odot
HS	H	1/2 circle	S	Cutting			\forall
HSG	H	1/2 circle	S	Cutting	G	heavy	\forall
HSP	H	1/2 circle	SP	Spatula			
HSR	H	1/2 circle	SR	Cutting taper			\bigcirc
HSRG	Н	1/2 circle	SR	Cutting taper	G	heavy	\bigcirc
KSP	К	1/4 circle	SP	Spatula			
TR	т	3/8 circle	R	Round-Bodied (taper)			\odot
TRM	Т	3/8 circle	R	Round-Bodied (taper)	Μ	Micropoint	\odot
TS	Т	3/8 circle	S	Cutting			\square
TSP	Т	3/8 circle	SP	Spatula			
TS-P	Т	3/8 circle	S	Cutting	Ρ	Precision Point	\square
TSR	Т	3/8 circle	SR	Cutting taper			\bigcirc
RR	R	straight	R	Round-Bodied (taper)			\odot
RS	R	straight	S	Cutting			V
FR	F	5/8 circle	R	Round-Bodied (taper)			\odot
HTT	н	1/2 circle	TT	Blunt-Point			0
HMR	HM	straight-curved	R	Round-Bodied (taper)			\odot
HMS	HM	straight-curved	S	Cutting			\forall
SKT	SK	straight-curved	Т	Cutting			\bigtriangledown





AssuCryl® Lactin (PGLA) braided, coated, synthetic absorbable						
Length	Thread Colour	Needle Code and Length in mm	USP	EP	REF	
		½ circle taper (Round-Bodied)				
75 cm 75 cm 90 cm 75 cm 90 cm 75 cm 90 cm	violet violet violet violet violet violet	HR-50	2 - 0 0 1 1 2 2	3 3.5 3.5 4 4 5 5	L4295 L4296 L4296N L4297 L4297N L4298 L4298N	
75 cm 75 cm 75 cm	violet violet violet	HR-65	2 - 0 0 1	3 3.5 4	L42985 L42986 L42987	
		$rac{1}{2}$ circle taper (Round-Bodied), heavy $$				
75 cm 75 cm 75 cm 75 cm	violet violet violet violet	HRG-27	3 - 0 2 - 0 0 1	2 3 3.5 4	L4334 L4335 L4336 L4337	
75 cm 75 cm 75 cm	violet violet violet	HRG-30	2 - 0 0 1	3 3.5 4	L43325 L43326 L43327	
75 cm 75 cm 90 cm 90 cm	violet violet violet violet	HRG-35	2 - 0 0 0 1	3 3.5 3.5 4	L43365 L43366 L43366N L43367N	
75 cm 90 cm 75 cm 90 cm 75 cm 90 cm 75 cm 90 cm	violet violet violet violet violet violet violet	HRG-38	2 - 0 2 - 0 0 1 1 2 2	3 3.5 3.5 4 4 5 5	L4345 L4345N L4346 L4346N L4347 L4347 L4347N L4348 L4348N	
75 cm 90 cm 75 cm 90 cm 75 cm 90 cm	violet violet violet violet violet violet	HRG-40	0 0 1 2 2	3.5 3.5 4 4 5 5	L43416 L43416N L43417 L43417N L43418 L43418N	
75 cm 75 cm 75 cm	violet violet violet	HRG-45	0 1 2	3.5 4 5	L43426 L43427 L43428	
75 cm 90 cm 75 cm 90 cm 75 cm 90 cm	violet violet violet violet violet violet	HRG-50	0 0 1 1 2 2	3.5 3.5 4 4 5 5	L43436 L43436N L43437 L43437N L43438 L43438 L43438N	
90 cm 100 cm	violet violet	HRG-80	1 1	4 4	L43487N L43487H	

Assut sutures 18

AssuCryl® MonoSlow (PDO) monofilament, synthetic absorbable					
Length	Thread Colour	Needle Code and Length in mm	USP	EP	REF
		3/8 circle reverse cutting \forall			
45 cm	violet	TS-12	6 - 0	0.7	MS4521F
45 cm	violet		5 - 0	1	MS4522F
45 cm	violet		4 - 0	1.5	MS4523F
75 cm	violet	TS-15	6 - 0	0.7	MS4531
75 cm	violet		5 - 0	1	MS4532
75 cm	violet		4 - 0	1.5	MS4533
45 cm	violet	TS-17	4 - 0	1.5	MS4543F
75 cm	violet		4 - 0	1.5	MS4543
45 cm	violet		3 - 0	2	MS4544F
75 cm	violet		3 - 0	2	MS4544
45 cm	violet	TS-19	4 - 0	1.5	MS4553F
75 cm	violet		4 - 0	1.5	MS4553
45 cm	violet		3 - 0	2	MS4554F
75 cm	violet		3 - 0	2	MS4554
75 cm	violet	TS-24	4 - 0	1.5	MS4563
75 cm	violet		3 - 0	2	MS4564
75 cm	violet		2 - 0	3	MS4565
75 cm	violet	TS-27	3 - 0	2	MS4574
75 cm	violet		2 - 0	3	MS4575
75 cm	violet	TS-30	3 - 0	2	MS4584
75 cm	violet		2 - 0	3	MS4585
75 cm	violet		0	3.5	MS4586
75 cm	violet	TS-38	3 - 0	2	MS4594
75 cm	violet		2 - 0	3	MS4595
75 cm	violet		0	3.5	MS4596
		Straight, cutting		•	
75 cm	violet	RS-58	3 - 0	2	MS4844
75 cm	violet		2 - 0	3	MS4845
75 cm	violet		0	3.5	MS4846
		3/8 circle reverse cutting Precision Point			
45 cm	violet	TS-12P	6 - 0	0.7	MS45201F
45 cm	violet		5 - 0	1	MS45202F
45 cm	violet		4 - 0	1.5	MS45203F
45 cm	violet	TS-15P	5 - 0	1	MS45302F
45 cm	violet		4 - 0	1.5	MS45303F
45 cm	violet		3 - 0	2	MS45304F
45 cm	violet	TS-19P	4 - 0	1.5	MS45503F
45 cm	violet		3 - 0	2	MS45504F
45 cm	violet	TS-24P	4 - 0	1.5	MS45603F
45 cm	violet		3 - 0	2	MS45604F
45 cm	violet	TS-27P	3 - 0	2	MS45704F
45 cm	violet	TS-35P	2 - 0	3	MS45865F

Silk	black brai	ided			
Length	Thread Colour	Needle Code and Length in mm	USP	EP	REF
		1/2 circle taper (Round-Bodied)			
75 cm 75 cm	black black	HR-13	5 - 0 4 - 0	1 1.5	601 602
75 cm 75 cm 75 cm 75 cm 75 cm	black black black black black black	HR-17	6 - 0 5 - 0 4 - 0 3 - 0 2 - 0	0.7 1 1.5 2 3	6231 603 604 605 6235
75 cm 75 cm 75 cm	black black black	HR-20	4 - 0 3 - 0 2 - 0	1.5 2 3	62353 62354 62355
75 cm 75 cm 75 cm 75 cm 75 cm 75 cm	black black black black black black black	HR-22	6 - 0 5 - 0 4 - 0 3 - 0 2 - 0 0	0.7 1 1.5 2 3 3.5	6241 6242 606 607 6245 6246
75 cm 75 cm 75 cm	black black black	HR-25	4 - 0 3 - 0 2 - 0	1.5 2 3	62453 62454 62455
75 cm 75 cm 75 cm 75 cm 75 cm 75 cm	black black black black black black black	HR-27	4 - 0 3 - 0 2 - 0 0 1 2	1.5 2 3 3.5 4 5	608 609 610 6256 6257 6258
75 cm 75 cm 75 cm 75 cm	black black black black black	HR-30	3 - 0 2 - 0 0 1	2 3 3.5 4	62554 62555 62556 62557
75 cm 75 cm 75 cm 75 cm 75 cm 75 cm	black black black black black black black	HR-32	3 - 0 2 - 0 0 1 2 3	2 3 3.5 4 5 6	6264 6265 6266 6267 6268 6269
75 cm 75 cm 75 cm	black black black	HR-35	2 - 0 0 1	3 3.5 4	62655 62656 62657
75 cm 75 cm 75 cm 75 cm 75 cm 75 cm	black black black black black black black	HR-38	3 - 0 2 - 0 0 1 2 3	2 3 3.5 4 5 6	611 612 613 6277 6278 6279

Silk

Silk black braided				
			Pre-cut sut	ures without needle
Number of Strands x Length	Thread Colour	USP	EP	REF
1 x 100 cm 1 x 100 cm	black black black black black black black black black	6 - 0 5 - 0 4 - 0 3 - 0 2 - 0 0 1 2 3	0.7 1 1.5 2 3 3.5 4 5 6	691 692 693 694 695 696 697 698 699
1 x 150 cm 1 x 150 cm 1 x 150 cm	black black black	3 - 0 2 - 0 0	2 3 3.5	60034 60035 60036
1 x 180 cm 1 x 180 cm 1 x 180 cm 1 x 180 cm 1 x 180 cm	black black black black black black	4 - 0 3 - 0 2 - 0 0 1	1.5 2 3 3.5 4	60043 60044 60045 60046 60047
5 x 75 cm 5 x 75 cm	black black black black black	4 - 0 3 - 0 2 - 0 0 1	1.5 2 3 3.5 4	681 682 683 684 685
17 x 50 cm 17 x 50 cm	black black black black black black black	5 - 0 4 - 0 3 - 0 2 - 0 0 1 2	1 1.5 2 3 3.5 4 5	671 672 673 674 675 676 677
13 x 60 cm 13 x 60 cm	black black black black black black black black	6 - 0 5 - 0 4 - 0 3 - 0 2 - 0 0 1 2	0.7 1 1.5 2 3 3.5 4 5	60001 60002 60003 60004 60005 60006 60007 60008



of Switzerland

Assut Medical Sàrl P.O. Box 5 CH-1009 Pully-Lausanne Switzerland Tel: ++ 41-21 - 728.64.35 Fax:++ 41-21 - 728.64.49 e-mail: info@assutsutures.com www.assutsutures.com

Specialties - Spécialités - Spezialitäten				
PTFE Pledgets				
Description Description Beschreibung	Unit per envelope Unité par sachet Einheit per Beutel	Product N° Produit N° Produkt N°	Additional information Information complémentaire Zusatzinformation	
7x3x1.5mm oval firm pledgets tampons ovales 7x3x1.5mm ovales Pledget 7x3x1.5mm	6 5	POF7315x6 POF7315x5		
9x5x1.5mm oval firm pledgets tampons ovales 9x5x1.5mm ovales Pledget 9x5x1.5mm	6	POF9515x6		
7x3x1.5mm rectangular firm pledgets tampons rectangulaires 7x3x1.5mm Rechteckiges Pledget 7x3x1.5mm	6 5	PRF7315x6 PRF7315x5		
9x5x1.5mm rectangular firm pledgets tampons rectangulaires 9x5x1.5mm Rechteckiges Pledget 9x5x1.5mm	6	PRF9515x6		



Assut Medical Sàrl P.O. Box 5 CH-1009 Pully-Lausanne Switzerland Tel: ++ 41-21 - 728.64.35 Fax:++ 41-21 - 728.64.49 e-mail: info@assutsutures.com www.assutsutures.com Assut Medical Sàrl P.O. Box 5 Av. de Lavaux 35 1009 Pully - Switzerland



Tel. +41 21 728 64 35 Fax +41 21 728 64 49 info@assutsutures.com www.assutsutures.com

LETTER OF AUTHORIZATION

To: whom it may concern

We, Assut Medical Sàrl located in Pully-Lausanne, Switzerland (tel.+41.21.728.64.35), are a manufacturer of sterile surgical sutures. Our general catalogue show only the most sold products worldwide but do not reflect the thousands of different sutures we are able to manufacture. We are a manufacturer of atraumatic needles (not an assembler like many other companies) and we are thus able to offer various products that sometimes are not mentioned in our general catalogue.

We, thus hereby authorize our representative for the Republic of Moldova – Medec Service SRL, or Chişinău, str. Academiei 3, of. 120, Republica Moldova, represented by Mr. Alexandru Captari to bid on their behalf and their own account in the Tender Nr. 21047547 with all our sterile surgical sutures including the following products manufactured by Assut Medical Sàrl, Switzerland which are not included in our catalog:

lot. 24 - REF CV739706x4 ,HSRG 50 (1/2c. cutting taper, 50mm) USP -6-, 4x45cm
lot. 25 - REF CV739707x4 (HSRG 50 (1/2c. cutting taper, 50mm) USP -7-, 4x45cm
REF CV73980x4 HSRG 50 (1/2c. cutting taper, 50mm) USP -7-, 4x75cm
lot. 30 - Silk black braided HR 25-25mm USP -0-, 75cm black REF 62456

Assut Medical Sàrl

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Pully, 03 December 2021



TECHNICAL SPECIFICATION / PRODUCT DESCRIPTION



PTFE Pledget

The Assut Pledgets are made of undyed non-absorbable polytetrafluorethylene (PTFE) polymers fibers. They are pre-punched and available in various sizes and shapes.

Name of the product	Assut Pledget
Manufacturer	Assut Medical Sàrl Av. De Rochettaz 57 CH-1009 Pully Switzerland
Factory location	CH-2606 Corgémont, Switzerland
Description of the product	PTFE Pledget – non-absorbable pre-punched
Composition	Polytetrafluorethylene (PTFE)
General characteristics	The Assut Pledgets are made of undyed non-absorbable polytetrafluorethylene (PTFE) polymers fibers. The Assut Pledgets are sold in packs or directly fixed to a sterile surgical suture. Refer to the catalogue for details.
Application	The Assut Pledgets are commonly used as a patch, a buttress for sutures, when non- absorbable sutures are used. The Assut Pledgets to be used are selected in accordance with the patient's condition, the surgeon's experience, the surgical procedure and the size of the wound.
Sterility	By ethylene oxide gas (EO)
Packaging	Primary packaging & Secondary packaging: Double envelope made in PET/PE Tyvek
Sizes	Available in various sizes and shapes including oval, round and rectangular
Shelf-life	5 years
Storing	Keep in a dry place away from direct heat.
CE Mark	CE-0344



TECHNICAL SPECIFICATION / PRODUCT DESCRIPTION

SURGICAL STEEL



Monofilament stainless steel with very high tensile strength and excellent knot security. This strand causes minimum tissue reaction.

Name of the product	Surgical Steel		
Manufacturer	Assut Medical Sàrl, Po Box 5,		
	Av. De Rochettaz 57,		
	CH-1009 Pully Switzerland		
Factory location	CH-2606 Corgémont, Switzerland		
Description of the product	Surgical Steel is a metallic, monofilament, non-absorbable suture made of Stainless steel.		
Colour	Natural (Steel)		
Chemical Composition	Stainless steel type 316 LVM compliant with ISO 5832-1		
General characteristics	Assut Surgical Steel is a metallic, monofilament, non-absorbable suture made of Stainle steel, with very high tensile strength and excellent knot security. This strand caus		
	minimum tissue reaction. Steel sutures are the most inert among all suture materials and provide maximum tensile strength. Tensile strength remains permanent.		
Application	Steel sutures are indicated for use in sternal closure		
Absorption	Non absorbable		
Sterility	By ethylene oxide gas (EO) or by gamma irradiation (R)		
Packaging	envelope made in PET/PE Tyvek		
Sizes	E.P. 6 to 9 USP -4- to -7-		
Shelf-life	5 years		
Storing	Keep in a dry place away from direct heat.		
CE Mark	CE-0344		
Other	Surgical Steel is available in different thicknesses and lengths with stainless-steel needles		
	in various types and sizes		
	See general "Assut sutures" catalogue		