



CERTIFICATE



This is to certify that the company

DemeTECH Corp.

14175 NW 60th Ave
Miami Lakes, FL, 33014
United States of America

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design, development and manufacturing of surgical sutures and distribution of surgical sutures, surgical meshes and hemostats.

-AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no. 291660 MDSAP16

Certificate unique ID 170761413

Effective date 2020-06-05

Expiry date 2023-06-04

Frankfurt am Main 2020-06-05



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.

Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



Annex to certificate

Certificate registration No.: 291660 MDSAP16

Certificate unique ID: 170761413

Effective date: 2020-06-05

DemeTECH Corp.

14175 NW 60th Ave
Miami Lakes, FL, 33014
United States of America

Audited site

DemeTECH Corp.
14175 NW 60th Ave
Miami Lakes, FL, 33014
United States of America

DUNS No., site scope and country-specific requirements

Design, development and manufacturing of
surgical sutures and distribution of surgical
sutures, surgical meshes and hemostats.
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)
DUNS No.: 039436691



Annex to certificate
Certificate registration No.: 291660 MDSAP16
Certificate unique ID: 170761413
Effective date: 2020-06-05

DemeTECH Corp.

14175 NW 60th Ave
Miami Lakes, FL, 33014
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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

DemeTECH Corp.

14175 NW 60th Ave
Miami Lakes, FL, 33014
United States of America

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

absorbable and non-absorbable surgical sutures as listed in the annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 291660 MR2

Certificate unique ID 170772617

Effective date 2020-11-27

Expiry date 2024-05-26

Frankfurt am Main 2020-11-27

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 291660 MR2
Certificate unique ID: 170772617
Effective date: 2020-11-27

DemeTECH Corp.

14175 NW 60th Ave
Miami Lakes, FL, 33014
United States of America

Device family	Device	Class
Non-absorbable Surgical Sutures	DemeLENE – Polypropylene	IIb
	DemeLENE – Polypropylene with Overstitch	IIb
	DemeBOND - Polyester (Braided)	IIb
	DemeSILK - Silk (Braided)	IIb
	DemeLON - Nylon (Monofilament)	IIb
	DemeLON Multi - Nylon Multifilament	IIb
	DemeSTEEL - Stainless Steel	IIb
	DemeTECH – PTFE Suture	IIb
Sterile Synthetic Absorbable Sutures	DemeSORB – Polyglycolic Acid (PGA)	III
	DemeCRYL – Polyglactin 910 (PGLA)	III
	DemeQUICK – RAPID ABSORBABLE (PGR)	III
	DemeDIOX – POLYDIOXANONE (PDO)	III
	DemeDIOX (with OverStitch™ anchor) - POLYDIOXANONE (PDO)	III
	DemeCAPRONE – POLIGLECAPRONE (MO)	III



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 2140-11-2020

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

DEMETECH CORP.
14175 NW 60th Ave
Miami Lakes, FL USA 33014

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from November 19, 2020 to November 18, 2022.





Certificate No. 2140-11-2020

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

DEMETECH CORP.
14175 NW 60th Ave
Miami Lakes, FL USA 33014

Name of Product(s)

DemeSILK - Silk Nonabsorbable Suture
DemeLON - Nylon Nonabsorbable Suture
DemeBOND - Polyester Nonabsorbable Suture
DemeLENE - Polypropylene Nonabsorbable Suture
DemeSORB - Absorbable Polyglycolic PGA Suture
DemeGUT Plain - Absorbable Plain Catgut Suture
DemeGUT Chromic - Absorbable Chromic Catgut Suture
DemeDIOX - Absorbable Polydioxanone Surgical Suture
DemeCAPRONE - Absorbable Poliglecaprone 25 Surgical Suture
DemeCRYL - Absorbable Poly(glycolic/L -lactide) PGLA Suture
DemeQUICK - Absorbable Poly(glycolic/L -lactide) PGLA Suture
DemeSTEEL - Nonabsorbable Stainless Steel Surgical Suture
DemeLENE MESH - Mesh Surgical Polymeric
DemeDIOX with Novathreads - Absorbable Polydioxanone Surgical Suture
DemeTECH PTFE - Polytetrafluoroethylene Nonabsorbable Suture
DemeDAC - Polyester Nonabsorbable Suture
DemeFORCE - UHMWPE Nonabsorbable Suture
DemeDIOX Barbed - Absorbable Polydioxanone Surgical Suture
DemeDIOX Barbed with Novathreads - Absorbable Polydioxanone Surgical Suture
SutureGard Suture Retention Device
HemiGard Adhesive Suture Retention Device
DemeMASK - Surgical Mask
DemeMASK - N95 Respirator
-----END OF PRODUCT LIST-----





DemeTECH[®]
"A Trusted Name in Medicine"

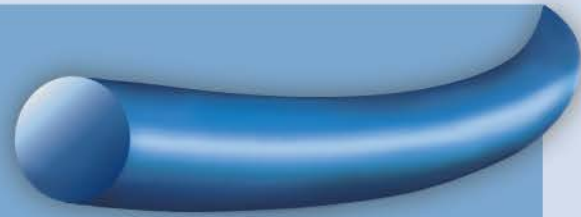


D E M E T E C H C o r p o r a t i o n U S A

DemeLENE™

Polypropylene Suture

DemeTech's Polypropylene Sutures



DemeTech's Polypropylene suture is a non-absorbable, sterile surgical suture composed of a synthetic linear polyolefin. DemeTech's Polypropylene is blue to enhance visibility in the body. DemeTech's Polypropylene suture elicits a minimal acute inflammatory reaction in the tissue, followed by gradual encapsulation of the suture by fibrous tissue.

Characteristics of DemeTech's Polypropylene Sutures:

- Extremely high tensile strength
- Very flexible
- Due to its synthetic and monofilament characteristic, DemeTech's Polypropylene elicits only minimal tissue reactivity.
- DemeTech's Polypropylene is highly ductile. It extends 30% prior to rupture of the thread, allowing for the post-operative swelling of tissue and avoiding possible strangulation of tissue.
- Allows for secured knot tying.
- Extremely smooth textile, resulting in minimal tissue trauma.

Indefinite

Tensile Strength

Monofilament





Blue

Material

Non
Absorbable
Suture

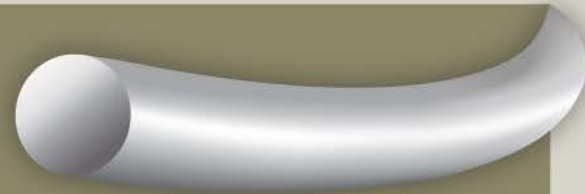
Absorption Profile

Needle Length	Cross Section	Curvature	Thread Length	USP	Code
Round Bodied Deme Blue 1/2 Circle (DOUBLE)					
 22 mm		1/2 Circle (DOUBLE)	90 cm	4/0	PM1094022C0P

DemeSTEEL™

Surgical Steel Suture

DemeTech's Steel Sutures



DemeTech's Surgical Steel sutures are nonabsorbable, sterile, surgical sutures composed of high quality stainless steel. Because of its high tensile strength, it exhibits very minimal loss over time and has low tissue reactivity. DemeTech's surgical steel is available as a monofilament.

Characteristics of DemeTech's Steel Sutures:

- Maximum tensile strength
- Most inert suture

Indefinite

Tensile Strength

Monofilament







Silver

Material

Non
Absorbable
Suture



Absorption Profile

Needle Length	Cross Section	Curvature	Thread Length	USP	Code
Taper Cutting Deme Silver 1/2 Circle					
		1/2 Circle	4x45 cm	7	SW4x110748B6P

Needle Length	Needle Code	Color	Thread Length	1	0
 <p>70 mm</p> <p>*Not to scale</p>	DXLH 	Blue	150 cm	PM590170B0P	PM590070B0P

Round Bodied 1/2 Circle (DOUBLE)



Needle Length	Needle Code	Color	Thread Length	7/0					
<div>11 mm</div> 	DRB-3 	Blue	60 cm	PM697011C0P					
Needle Length	Needle Code	Color	Thread Length	4/0		5/0		6/0	
<div>13 mm</div> 	DRB-2 	Blue	45 cm			PM195013C0P		PM196013C0P	
			60 cm	PM694013C0P		PM695013C0P			
			75 cm			PM295013C0P		PM296013C0P	
			90 cm	PM1094013C0P					
Needle Length	Needle Code	Color	Thread Length	2/0	3/0	4/0	5/0	6/0	
<div>17 mm</div> 	DRB-1 	Blue	45 cm			PM194017C0P	PM195017C0P		
			60 cm				PM695017C0P		
			75 cm	PM292017C0P	PM293017C0P	PM294017C0P	PM295017C0P	PM296017C0P	
			90 cm	PM1092017C0P	PM1093017C0P	PM1094017C0P	PM1095017C0P	PM1096017C0P	
Needle Length	Needle Code	Color	Thread Length	3/0			4/0		
<div>20 mm</div> 	DSH-2 	Blue	75 cm	PM293020C0P			PM294020C0P		
			90 cm	PM1093020C0P			PM1094020C0P		
Needle Length	Needle Code	Color	Thread Length	3/0			4/0		
<div>22 mm</div> 	DSH-1 	Blue	75 cm	PM293022C0P			PM294022C0P		
Needle Length	Needle Code	Color	Thread Length	2/0	3/0	4/0	5/0		
<div>26 mm</div> 	DSH 	Blue	75 cm	PM292026C0P	PM293026C0P		PM295026C0P		
			90 cm	PM1092026C0P	PM1093026C0P	PM1094026C0P			
			120 cm	PM1292026C0P	PM1293026C0P				

