

Ref. : DECCE139G-00

DECCE139G-00 et/and DECCE070G-31 et/and DECCE137G-00 annulent et remplacent (*Cancel and replace*) : DECCE070G-30

DECLARATION CE DE CONFORMITE

EC DECLARATION OF CONFORMITY

Nous

We

PETERS SURGICAL

Déclarons sous notre entière responsabilité que les dispositifs médicaux :

Declare under our sole responsibility that the medical devices:

Sutures et ligatures chirurgicales résorbables
Absorbable surgical sutures and ligatures

(voir liste des dispositifs médicaux ci-joint)

(Refer to list of medical devices here attached)

sont en conformité avec les exigences essentielles figurant à l'annexe 1 du décret n° 95.292 du 16 mars 1995 et qui leur sont applicables, transposant en droit français la Directive 93/42/CEE du conseil du 14 juin 1993 relative aux dispositifs médicaux.

comply with the essential requirements of the annex 1 which apply to them from the decree n° 95.292 of March 16, 1995 transposing in French law the council Directive 93/42/EEC June 14, 1993 concerning medical devices.

La conformité de ces produits de classes III (selon les règles de classification de l'annexe IX et l'usage prévu par le fabricant) a été établie conformément à l'annexe II points 3 et 4 de la directive 93/42/CEE.

The conformity of these classes III products (classification rules of annex IX of above Directive) has been assessed according to annex II sections 3 and 4 of the directive 93/42/EEC.

Certificats délivrés par l'organisme notifié GMED (enregistré sous le n° 0459) – 1 rue Gaston Boissier – 75015 Paris – France

Certificates delivered by notified body GMED (registered under number 0459) – 1 rue Gaston Boissier – 75015 Paris – France

- Attestation CE n° 36018
- Attestation CE n° 9072

- EC certificate n° 36018
- EC certificate n° 9072

Date : 2019-10-15

Le représentant du fabricant / *On behalf of the manufacturer:*


Marie-Noëlle EROUT
Directrice Qualité et Affaires Réglementaires
/ Quality and Regulatory Affairs Director

GMED (0459) reconnaît que son certificat CE
est valide pour les dispositifs médicaux décrits
.....
GMED (0459) recognizes that its EC certificate
is valid for the medical devices listed

27 NOV. 2019

REFERENCE	DESIGNATION	CLASSE CLASS	ATTESTATIONS CE EC CERTIFICATES	DOSSIER TECHNIQUE TECHNICAL FILE
12xxx	OPTIME® R	III	II.3 36018 II.4 :9072	DT/SU/07
14xxx	MONOTIME®	III	II.3 36018 II.4 :9072	DT/SU/07
15xxx	ADVANTIME®	III	II.3 36018 II.4 :9072	DT/SU/07
18xxx	OPTIME®	III	II.3 36018 II.4 :9072	DT/SU/07
39xxx	GLACTIME®	III	II.3 36018 II.4 :9072	DT/SU/07
81xx	SINUSORB® PGA	III	II.3 36018 II.4 :9072	DT/SU/07
S00Axxx	DENTABS	III	II.3 36018 II.4 :9072	DT/SU/07

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Range			Packaging		Thread			Needle				
Range	Range code	Molecule	Unit qty per box	Sub family	Thread qty	Thread Size (USP)	Thread length (cm)	Needles quantity	Needle length (mm)	Needle curvature	Needle tip	Needle color
Optime®	18....	PGA braid + coating with epsilon-caprolactone and calcium stearate (violet dyed or undyed)	36	Alu for suture	1		45 to 150	1 or 2 standard or loop sutures	8 to 70	1/2 3/8 5/8 straight	taper (R) lasershape taper cutting (KL) cutting (T) blunt (mousse/BP)	silver or Extrablack
			36	Alu for strands	up to 12 (depending of the length (see length description))	6/0 to 2	For USP 2: up to 3,5m (5 x 70) Up to USP 1: up to 5,4m (12 x 45)	without	NA	NA	NA	NA
			24	Alu for Filpak	1	5/0 to 2	150 to 250	without	NA	NA	NA	NA
Optime® Septodont	18... SD	PGA braid + coating with epsilon-caprolactone and calcium stearate (violet dyed or undyed)	12	Alu for suture	1	6/0 to 2	45 to 150	1 or 2 standard or loop sutures	8 to 70	1/2 3/8 5/8 straight	taper (R) lasershape taper cutting (KL) cutting (T) blunt (mousse/BP)	silver or Extrablack

Range		Packaging		Thread			Needle				
Dentabs	S00A...	12	Alu for suture	1	5/0 to 3/0	70	1	11 to 20	1/2 3/8	cutting (T)	silver
Optime® R Gamma	12...	36	Alu for suture	1	6/0 to 1	45 to 90	1	11 to 60	1/2, 3/8 straight	taper (R) taper cutting (KL) cutting (T) Extracut (XT)	silver or Extrablack
Optime® R OE	12...M	36	Alu for suture	1	6/0 to 1	45 to 90	1	11 to 60	1/2,3/8straight	taper (R)taper cutting (KL)cutting (T)Extracut (XT)	silver or Extrablack
Advantime®	15...	36	Alu for suture	1	6/0 to 1	45 to 110	1 or 2	10 to 60	1/2, 3/8 5/8 straight	taper (R), taper cutting (KL) cutting (T) Extracut (XT)	silver
		24	Alu for Filpak	1	3/0 to 1	250	without	NA	NA	NA	NA





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Range		Packaging		Thread			Needle				
Monotime®	14...	36	Alu for suture	1	7/0 to 2	30 to 150	1 or 2 standard or loop sutures	6,4 to 60	1/2, 3/8 straight	taper (R) taper cutting (KL), cutting (T)	silver or Extrablack
Sinusorb® PGA	81...	12	Alu for suture	1	7/0 to 4/0	15 to 45	1	4 to 19	1/2, 1/4 3/8	taper (R) Spatula (SP), cutting (T)	silver
		12	Alu for dogbone	1	10/0 to 4/0		1 or 2				
Glactime®	39...	36	Alu for suture	1	6/0 to 2	45 to 150	1 or 2 standard or loop sutures	10 to 70	1/2 3/8 5/8 straight	taper (R), Lasershape taper cutting (KL) cutting (T) blunt (mousse)	silver or Extrablack
		24	Alu for Filpak	1	5/0 to 2	150 to 250	without	NA	NA	NA	NA

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