

**Ref. : DECCE070G-33**

DECCE070G-33 annule et remplace (Cancels and replaces) : DECCE070G-32

**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 non résorbables**  
*Non 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 classe IIb (selon les règles de classification de l'annexe IX et l'usage prévu par le fabricant) a été établie conformément à l'annexe II point 3 de la directive 93/42/CEE.

*The conformity of these class IIb products (classification rules of annex IX of above Directive) has been assessed according to annex II section 3 of the directive 93/42/EEC.*

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

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

- Attestation CE n° 36016
- Document complémentaire n°37407

- *EC certificate no. 36016*
- *Additional document n°37407*

Date : 31/12/2020

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

Marie COMPAGNON-RIOBÉ  
Directrice Affaires Réglementaires Groupe  
Group Regulatory Affairs Director

DocuSigned by:

*Fatima Zahra Meskini*

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| REFERENCE    | DESIGNATION    | CLASSE<br>CLASS | ATTESTATIONS CE<br>EC CERTIFICATES | DOSSIER TECHNIQUE<br>TECHNICAL FILE |
|--------------|----------------|-----------------|------------------------------------|-------------------------------------|
| 25xxx        | Soie / Silk    | IIb             | II.3 36016                         | DT/SU/01                            |
| 31xxx        | Acier          | IIb             | II.3 36016                         | DT/SU/01                            |
| 84xx<br>85xx | Nylon          | IIb             | II.3 36016                         | DT/SU/01                            |
| 87xx         | Polypropylen   | IIb             | II.3 36016                         | DT/SU/01                            |
| 87xxx        | FILAPEAU®      | IIb             | II.3 36016                         | DT/SU/01                            |
| 88xx         | SOIE / SILK    | IIb             | II.3 36016                         | DT/SU/01                            |
| LECSxxx      | Soie ARCHIMED® | IIb             | II.3 36016                         | DT/SU/01                            |
| S00Nxxx      | POLYEST        | IIb             | II.3 36016                         | DT/SU/01                            |

DocuSigned by:

*Fatima Zahra Meskini*

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| Range         |                |                                         | Packaging             |                       | Thread     |                   |                    | Needle           |                    |                          |                                             |              |
|---------------|----------------|-----------------------------------------|-----------------------|-----------------------|------------|-------------------|--------------------|------------------|--------------------|--------------------------|---------------------------------------------|--------------|
| Range         | Range code     | Molecule                                | Unit quantity per box | Sub family            | Thread qty | Thread Size (USP) | Thread length (cm) | Needles quantity | Needle length (mm) | Needle curvature         | Needle tip                                  | Needle color |
| Acier         | 31....         | 316LVM monofilament (undyed)            | 12                    | Pack DA Acier         | 4          | 3/0 to 8          | 45                 | 2                | 20 to 50           | 1/2<br>3/8<br>straight   | 3 Faces cutting (T)                         | silver       |
|               |                |                                         | 12                    | Pack SA Acier         | 1 to 8     |                   | 40 to 75           | 1                |                    |                          |                                             |              |
|               |                |                                         | 24                    | SA Acier              | 1          |                   | 40 to 240 (6 x 40) | without          | NA                 | NA                       | NA                                          | NA           |
|               |                |                                         | 24                    | Pack strands Acier    | 1 to 6     |                   |                    |                  |                    |                          |                                             |              |
| Filapeau      | 87...          | PA 6 Monofilament (blue dyed or undyed) | 36                    | Onepak (carton)       | 1          | 7/0 to 2          | 40 to 90           | 1 or 2           | 11 to 65           | 1/2<br>3/8<br>straight   | taper (R), cutting (T / KT), Extracut (XT), | silver       |
|               |                |                                         | 12                    |                       |            |                   |                    |                  |                    |                          |                                             |              |
|               |                |                                         | 24                    | Filpak (reel)         | 1          | 4/0 to 2          | 250                | without          | NA                 | NA                       | NA                                          | NA           |
|               |                |                                         | 24                    | Pack strands Filapeau | 6          | 3/0 to 3          | 240 (6 x 40)       | without          | NA                 | NA                       | NA                                          | NA           |
| Nylon (Ophta) | 84... or 85... | PA 6.6 Monofilament (black dyed)        | 12                    | Onepak (carton)       | 1          | 6/0 to 4/0        | 10 to 45           | 1 or 2           | 4 to 16            | 1/2<br>1/4<br>3/8<br>BIC | Taper (R) cutting (T), spatula (SP)         | silver       |
|               |                |                                         | 12                    | Blister               |            | 11/0 to 5/0       |                    |                  |                    |                          |                                             |              |

| Range                 |                                                    |                                                    | Packaging             |                    | Thread     |                   |                    | Needle           |                    |                            |                                                                 |              |
|-----------------------|----------------------------------------------------|----------------------------------------------------|-----------------------|--------------------|------------|-------------------|--------------------|------------------|--------------------|----------------------------|-----------------------------------------------------------------|--------------|
| Range                 | Range code                                         | Molecule                                           | Unit quantity per box | Sub family         | Thread qty | Thread Size (USP) | Thread length (cm) | Needles quantity | Needle length (mm) | Needle curvature           | Needle tip                                                      | Needle color |
| Polyest               | S00N<br>(for black PET)<br>S00G<br>(for green PET) | PET braid + silicone coating (black or green dyed) | 12                    | Onepak (carton)    | 1          | 4/0 to 2/0        | 70 to 75           | 1                | 16 to 20           | 1/2<br>3/8                 | cutting (T)                                                     | silver       |
| Polypropylene (ophta) | 87...                                              | PP monofilament (blue dyed)                        | 12                    | Onepak (carton)    | 1          | 6/0 to 5/0        | 10 to 75           | 1 or 2           | 4 to 16            | 1/2<br>3/8<br>1/4 straight | Taper (R)<br>taper cutting (KL)<br>cutting (T),<br>spatula (SP) | silver       |
|                       |                                                    |                                                    | 12                    | Blister            |            | 10/0 to 5/0       |                    |                  |                    |                            |                                                                 |              |
| Soie / Silk (CG)      | 25..                                               | Silk braid + wax coating (black dyed)              | 36                    | Onepak (carton)    | 1          | 6/0 to 2          | 45 to 90           | 1 or 2           | 9 to 65            | 1/2<br>3/8 straight        | cutting (T),<br>Taper (R )                                      | silver       |
|                       |                                                    |                                                    | 12                    |                    |            |                   |                    |                  |                    |                            |                                                                 |              |
|                       |                                                    |                                                    | 24                    | Onepak for strands | 15         | 4/0 to 1          | 900 (15 x 60)      | Without          | NA                 | NA                         | NA                                                              | NA           |
|                       |                                                    |                                                    | 24                    | Filpak (reel)      | 1          | 6/0 to 2          | 250                | Without          | NA                 | NA                         | NA                                                              | NA           |

| Range                  |            | Packaging                             |                       | Thread          |            |                   | Needle             |                  |                    |                  |                                                        |              |
|------------------------|------------|---------------------------------------|-----------------------|-----------------|------------|-------------------|--------------------|------------------|--------------------|------------------|--------------------------------------------------------|--------------|
| Range                  | Range code | Molecule                              | Unit quantity per box | Sub family      | Thread qty | Thread Size (USP) | Thread length (cm) | Needles quantity | Needle length (mm) | Needle curvature | Needle tip                                             | Needle color |
| Silk PR                | 25...BQ R  |                                       | 36                    | Onepak (carton) | 1          | 6/0 to 2          | 45 to 90           | 1 or 2           | 9 to 65            | 1/2 3/8 straight | cutting (T), taper (R)                                 | silver       |
| Silk SD                | 25...SD    |                                       | 12                    | Onepak (carton) | 1          | 6/0 to 2          | 45 to 90           | 1 or 2           | 9 to 65            | 1/2 3/8 straight | cutting (T), taper (R)                                 | silver       |
| Soie Dentaire Archimed | LECS...    | Silk braid + wax coating (black dyed) | 36                    | Onepak (carton) | 1          | 5/0 to 2/0        | 45                 | 1                | 13 to 24           | 1/2 3/8          | cutting (T)                                            | silver       |
|                        |            |                                       | 12                    |                 |            |                   |                    |                  |                    |                  |                                                        |              |
| Soie / Silk (ophtha)   | 88...      | Silk braid + wax coating (black dyed) | 12                    | Onepak (carton) | 1          | 6/0 to 4/0        | 15 to 45           | 1 or 2           | 6 to 16            | 1/2 1/4 3/8      | cutting (T), taper (R) taper cutting (KL) spatula (SP) | silver       |
|                        |            |                                       | 12                    | Blister         |            | 7/0 to 5/0        |                    |                  |                    |                  |                                                        |              |

NOTE: PR signifie que ces références sont mise à disposition des utilisateurs, sous une autre marque.

NOTE: PR stands for a private label

NOTE2: SD signifie ces références sont mise à disposition des utilisateurs, sous une autre marque.

NOTE2: SD stands for another private label