



Reg. Number	18029 - M	Valid From	2020-05-18
First issue date	2014-02-21	Last change date	2020-05-18
Valid until	2023-05-20		

Previous expiry date

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

LANDANGER S.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design management, production management of active and non active surgical instruments and endoscopy instruments. Design and production management for Class I non active surgical instruments, endoscopy instruments and containers for sterilization. Distribution of surgical instruments, endoscopy instruments and container for sterilization.

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

The date of issuance of this certificate is the date of first issue by another accredited body

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl

Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: info@kiwacermet.it

www.kiwa.it

CERMET

LANDANGER S.A.

Registered Headquarters

- 217-219 Rue du Faubourg Saint Honoré 75008 Paris France

Certified Sites

- Z.I. La vendue 52000 Chaumont France





Reg. Numero / Reg. Number	MED 31590	Revisione / Revision	0
Primo rilascio / First issue date	2020-07-09	Valido da / Valid from	2020-07-09
Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2020-07-09

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Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

LANDANGER S.A.

Sede Operativa / Operative Site:

Z.I. La vendue
52000 Chaumont - Francia

Sede Legale / Legal Site

217-219 Rue du Faubourg Saint Honoré
75008 Paris - Francia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II escluso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici/ *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Accessories for surgical instruments
Active surgical instruments
Anti-fog solution for endoscope
Bipolar instruments for surgery
Endoscopic instruments for uro-gynecology
Monopolar instrument for surgery
Non active surgical instruments
Suction devices
Suction-irrigation devices

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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Rif. rapporto di audit/ *Ref. audit report:* del/dated 08-09-10/04/2020

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* del/dated 18/06/2019, 23/01/2020, 14/02/2020

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:10/07/2020 08:45:44



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number

MED 31590

Revisione /
Revision

0

Primo rilascio /
First issue date

2020-07-09

Valido da /
Valid from

2020-07-09

Scadenza /
Valid until

2024-05-26

Ultima modifica /
Last change date

2020-07-09

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CERTIFICATE

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Accessories for surgical instruments

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Camera Sleeve

Tipologia / Medical Devices:

Active surgical instruments

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 1104

Modello / Model:

Active Sheath

Tipologia / Medical Devices:

Anti-fog solution for endoscope

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0108, MDS 7006 Radiation

Modello / Model:

Anti-fog solution 5 ml with sponge

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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:10/07/2020 08:46:03



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number MED 31590

Primo rilascio /
First issue date 2020-07-09

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Valid until 2024-05-26

Revisione /
Revision 0

Valido da /
Valid from 2020-07-09

Ultima modifica /
Last change date 2020-07-09

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CERTIFICATE

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Bipolar instruments for surgery

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1104

Modello / Model:

Reusable working elements for bipolar instruments

Classe di rischio / Risk class:

II b

Codice NANDO / NANDO codes:

MD 0106

Modello / Model:

Reusable accessories for bipolar instruments

Codice NANDO / NANDO codes:

MD 1104

Modello / Model:

Reusable surgical instrument for endoscopy and open surgery

Codice NANDO / NANDO codes:

MD 1104, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Disposable bipolar instrument for endoscopy

Tipologia / Medical Devices:
Endoscopic instruments for uro-gynecology

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106

Modello / Model:

Reusable albarra deflector

Chief Operating Officer
Giampiero Belcredi

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Data:10/07/2020 08:46:22



Organismo Notificato n. 0476
Notified Body nr. 0476

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Reg. Numero / <i>Reg. Number</i>	MED 31590	Revisione / <i>Revision</i>	0
Primo rilascio / <i>First issue date</i>	2020-07-09	Valido da / <i>Valid from</i>	2020-07-09
Scadenza / <i>Valid until</i>	2024-05-26	Ultima modifica / <i>Last change date</i>	2020-07-09

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Allegato tecnico al Certificato/ *Technical sheet enclosed to the Certificate*

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*

Endoscopic instruments for uro-gynecology

Modello / Model:

Reusable cystoscope sheath

Modello / Model:

Reusable guide tube for continuous irrigation

Modello / Model:

Reusable resectoscope sheath

Modello / Model:

Reusable urethrotome sheath

Tipologia / *Medical Devices:*

Monopolar instrument for surgery

Classe di rischio / *Risk class:*

II a

Codice NANDO / *NANDO codes:*

MD 0106

Modello / Model:

Non active reusable accessory for monopolar surgical instruments

Codice NANDO / *NANDO codes:*

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Non active disposable accessory for monopolar surgical instruments

Classe di rischio / *Risk class:*

II b

Codice NANDO / *NANDO codes:*

MD 1104

Modello / Model:

Active accessories for monopolar instruments

Modello / Model:

Monopolar active surgical instruments

Chief Operating Officer

Giampiero Belcredi

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Data:10/07/2020 08:46:44



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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Last change date 2020-07-09

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Monopolar instrument for surgery

Codice NANDO / NANDO codes:
MD 1104, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:
Disposable active accessories for monopolar instruments

Modello / Model:
Disposable monopolar active surgical instruments

Tipologia / Medical Devices:
Non active surgical instruments

Classe di rischio / Risk class:
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:
Smoke evacuator

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 0102, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:
Insufflation needle

Codice NANDO / NANDO codes:
MD 0106

Modello / Model:
Non active reusable Trocar and Sheath

Modello / Model:
Reusable Veres needle

Codice NANDO / NANDO codes:
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Chief Operating Officer
Giampiero Belcredi

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Data:10/07/2020 08:47:12



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Kiwa Cermet Italia S.p.A.
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Revision 0

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Last change date 2020-07-09

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CERTIFICATE

**Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate**

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Non active surgical instruments

Modello / Model:
Insufflation tubing

Modello / Model:
Non active single use Trocar and Sheath

Modello / Model:
Retrieval bag

Modello / Model:
Wound Retractor

Tipologia / Medical Devices:
Suction devices

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 0106

Modello / Model:
Reusable suction tubes for open surgery

Codice NANDO / NANDO codes:
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:
Disposable suction tubes for open surgery

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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:10/07/2020 08:47:37



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number MED 31590

Revisione /
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Valid from 2020-07-09

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CERTIFICATE

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:
Suction-irrigation devices

Classe di rischio / Risk class:
II a

Codice NANDO / NANDO codes:
MD 0106

Modello / Model:
Reusable cannulae

Modello / Model:
Reusable endoscopic suction-irrigation devices

Codice NANDO / NANDO codes:
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:
Disposable endoscopic suction-irrigation devices

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:10/07/2020 08:48:00



Organismo Notificato n. 0476
Notified Body nr. 0476



DECLARATION DE CONFORMITE



DECLARATION OF CONFORMITY

Nous, Société / *We, Company* **LANDANGER**

Adresse de contact / *Contact address*: **ZI la Vendue, 52000 Chaumont – France**

Tél. : **03 25 02 10 10** – Fax : **03 25 02 10 20**

E-mail : **landanger@landanger.com**

Siège social / *Registered place of business*: **217-219 rue du faubourg Saint Honoré, 75008 Paris - France**

EN TANT QUE FABRICANT, DÉCLARONS SOUS NOTRE PROPRE RESPONSABILITE QUE LES
DISPOSITIFS MÉDICAUX :

AS MANUFACTURER, HEREBY DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE MEDICAL DEVICES:

« **Accessories for surgical instruments**

Active surgical instruments

Anti-fog solution for endoscope

Bipolar instruments for surgery

Endoscopic instruments for uro-gynecology

Monopolar instrument for surgery

Non active surgical instruments

Suction devices

Suction-irrigation devices.»

CLASSE Is, IIa et IIb

Voir liste jointe de 31 pages en annexe / see 31 pages enclosed list

✓ Sont conformes au certificat KIWA Cermet Italia SpA – Via Cadriano, 23 – 40057 Granarolo dell’Emilia (BP) - Italia, CE 0476 n° MED 31590. délivrée le 10 JUILLET 2020.

They are complying with the certificate KIWA Cermet Italia SpA – Via Cadriano, 23 – 40057 Granarolo dell’Emilia (BP) - Italia, CE 0476 n° MED 31590 delivered on July 10th 2020 .

✓ Ne sont pas fabriqués à partir de tissus d’origine animale tels que visés dans le règlement européen 722/2012.

Are not made from animal tissues as directed in the European Regulation 722/2012.

✓ Ne contiennent pas de substances dérivées du sang humain tels que visées à la Directive Européenne 93/42/CEE.

Do not contain substances produced from human blood as directed in the European Directive 93/42/CEE.

✓ Satisfont aux dispositions du livre II du code de la santé publique.

They satisfy the arrangements of the public health book II.

Sont conformes à la Directive Européenne 93/42/CEE, et ses amendements, sur les dispositifs médicaux Annexe II (point 3) et appartiennent à la classe **Is, IIa et IIb**.

*Are complying with the European Directive 93/42/CEE, and its amemdments, concerning medical devices Appendix II (point 3) and belong to class **Is, IIa and IIb**.*

☞ De ce fait, je m’estime remplir les obligations des exigences essentielles selon l’Annexe I.

Consequently, I commit myself to meet all the essential requirements obligations according to Appendix I.

Chaumont, le *10 JUILLET 2020*

Le Directeur d’établissement,

Director

Didier DEBLAIZE

L A N D A N G E R

LANDANGER

Déclaration de conformité
Declaration of conformity

Déclaration de conformité
Declaration of conformity



Nous, Société / *We, Company* **LANDANGER**

Adresse de contact / *Contact address*: **ZI la Vendue, 52000 Chaumont – France**

Tél. : **03 25 02 10 10** – Fax : **03 25 02 10 20**

E-mail : **landanger@landanger.com**

Siège social / *Registered place of business*: **217-219 rue du faubourg Saint Honoré, 75008 Paris - France**

Enregistré sous le numéro / *Registered under the number*: **SRN: FR-MF-000000468**

EN TANT QUE FABRICANT, DÉCLARONS SOUS NOTRE PROPRE RESPONSABILITE QUE LES
DISPOSITIFS MÉDICAUX :

AS MANUFACTURER, HEREBY DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE MEDICAL DEVICES:

Gamme : Instrumentation Endoscopique
Range : Endoscopic instrumentation

Voir liste jointe de 64 pages en annexe du 25/05/2021 / See 64 pages enclosed list from the 25/05/2021.

- ✓ Sont conformes à la Directive Européenne 93/42/CEE, et ses amendements, sur les dispositifs médicaux et appartiennent à la classe **I**.
Are complying with the European Directive 93/42/CEE, and its amendments, concerning medical devices I.
- ✓ Ne sont pas fabriqués à partir de tissus d'origine animale tels que visés dans le règlement européen 722/2012.
Are not made from animal tissues as directed in the European Regulation 722/2012.
- ✓ Ne contiennent pas de substances dérivées du sang humain tels que visées à la Directive Européenne 93/42/CEE.
Do not contain substances produced from human blood as directed in the European Directive 93/42/CEE.
- ✓ Satisfont aux dispositions du livre II du code de la santé publique.
They satisfy the arrangements of the public health book II.
- ☞ De ce fait, je m'estime remplir les obligations des exigences essentielles selon l'Annexe I.
Consequently, I consider myself to meet all the essential requirements obligations according to Appendix I.

Chaumont, le 25/05/2021

Le Directeur d'établissement,
Managing Director
Didier Deblaize

LANDANGER 0

LANDANGER

Déclaration de conformité
Declaration of conformity

Déclaration de conformité
Declaration of conformity



Nous, Société / *We, Company* **LANDANGER**

Adresse de contact / *Contact address*: **ZI la Vendue, 52000 Chaumont – France**

Tél. : **03 25 02 10 10** – Fax : **03 25 02 10 20**

E-mail : [**landanger@landanger.com**](mailto:landanger@landanger.com)

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Enregistré sous le numéro / *Registered under the number*: **SRN: FR-MF-000000468**

EN TANT QUE FABRICANT, DÉCLARONS SOUS NOTRE PROPRE RESPONSABILITE QUE LES
DISPOSITIFS MÉDICAUX :

AS MANUFACTURER, HEREBY DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE MEDICAL DEVICES:

Gamme : Instrumentation générale

Range :General instrumentation

Voir liste jointe de 278 pages en annexe du 25/05/2021 / See 278 pages enclosed list from the 25/05/2021.

- ✓ Sont conformes à la Directive Européenne 93/42/CEE, et ses amendements, sur les dispositifs médicaux et appartiennent à la classe **I**.
Are complying with the European Directive 93/42/CEE, and its amendments, concerning medical devices I.
 - ✓ Ne sont pas fabriqués à partir de tissus d'origine animale tels que visés dans le règlement européen 722/2012.
Are not made from animal tissues as directed in the European Regulation 722/2012.
 - ✓ Ne contiennent pas de substances dérivées du sang humain tels que visées à la Directive Européenne 93/42/CEE.
Do not contain substances produced from human blood as directed in the European Directive 93/42/CEE.
 - ✓ Satisfont aux dispositions du livre II du code de la santé publique.
They satisfy the arrangements of the public health book II.
- ☞ De ce fait, je m'estime remplir les obligations des exigences essentielles selon l'Annexe I.
Consequently, I consider myself to meet all the essential requirements obligations according to Appendix I.

Chaumont, le 25/05/2021

Le Directeur d'établissement,
Managing Director
Didier Deblaize

LANDANGER





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DATE
01/03/2022

MD2C01000
SC MEDEC SERVICE , SRL
ACADEMIEI 3 STR., OF. 120
MD-2028CHISINAU
MOLDAVIE

MD2C01000
SC MEDEC SERVICE , SRL
ACADEMIEI 3 STR., OF. 120
MD-2028 CHISINAU
MOLDAVIE

	Item Code	Qté	PU H.T.	Discoun	PU H.T.	Montant
	Description		Tarif		NET	H.T.
	D036030 HARTMANN MICRO FORCEPS SERRATED JAWS 0,8X4MM WL 75MM Garantie : 5 ans	1				
	I182057 SUCTION CANNULA ANGLED CONICAL L:115MM D:3.0MM Garantie : 5 ans	2				
	B254805 CURVED SCISSORS L:105MM POINTED VERY FINE Garantie : 5 ans	2				
	J170901 WEIL-BLAKESLEY LAMINECTOMY RONGEUR L:120MM STRAIGHT JAWS 3.0X10MM Garantie : 5 ans	1				
	J170902 WEIL-BLAKESLEY LAMINECTOMY RONGEUR L:120MM ANGLED JAWS UPWARD 45° 3.0X10MM Garantie : 5 ans	1				

LANDANGER







1947




*«L'instrument des instruments
c'est la main.»
Aristote*

WEIL-BLAKESLEY




Largueur de mors Width of jaw Anchura de boca	Longueur tige Shaft length Largo del tallo	Droite Straight Recta	Vers le haut Upward Hacia arriba
 3,0 x 10 mm	12 cm - 4 ^{3/4} "	J170901	J170902
 3,5 x 10 mm	12 cm - 4 ^{3/4} "	 J170903	J170904
 4,5 x 10 mm	12 cm - 4 ^{3/4} "	J170905	J170906
 5,0 x 10 mm	12 cm - 4 ^{3/4} "	J170907	J170908
 6,0 x 10 mm	12 cm - 4 ^{3/4} "	J170909	-

8 cm - 3 1/4"



Micro-pince
Micro-forceps
Micro-pinzas

D036010

1,6 x 7,0 mm **D036010** 

0,7 x 3,5 mm **D036020**

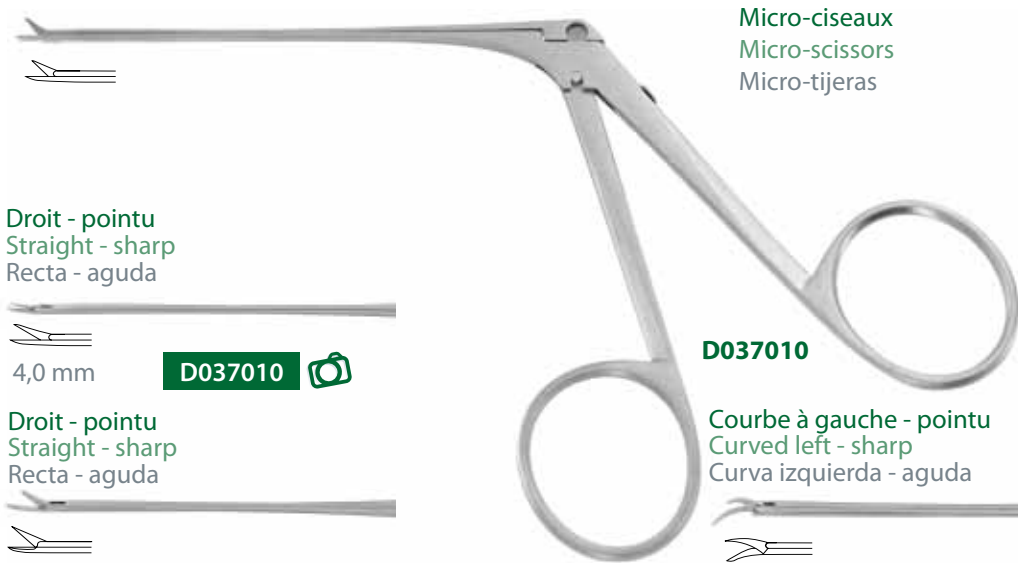
0,8 x 4,0 mm **D036030**

0,6 x 4,0 mm **D036040**

0,4 x 4,0 mm **D036050**

BELLUCI


8 cm - 3 1/4"



Micro-ciseaux
Micro-scissors
Micro-tijeras

D037010

Droit - pointu
Straight - sharp
Recta - aguda

4,0 mm **D037010** 

Droit - pointu
Straight - sharp
Recta - aguda

5,5 mm **D037020**

Coudé haut - pointu mousse
Angled upward - sharp blunt
Angulada arriba - aguda roma

5,5 mm **D037030**

Courbe à gauche - pointu
Curved left - sharp
Curva izquierda - aguda

5,5 mm **D037040**

Courbe à droite - pointu
Curved right - sharp
Curva derecha - aguda

5,5 mm **D037050**


LANDANGER

Aspirateurs - Suction-tubes - Tubos de aspiración


L: 90 mm

I182050	Ø 1.0 mm
I182051	Ø 1.5 mm
I182052	Ø 2.0 mm

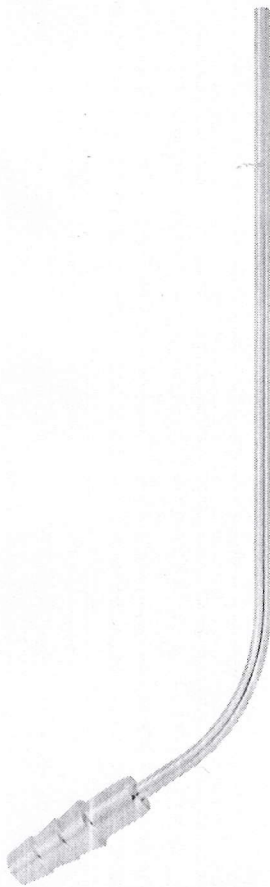
L: 90 mm

I182057	Ø 3.0 mm
 I182058	Ø 3.5 mm
I182059	Ø 4.5 mm

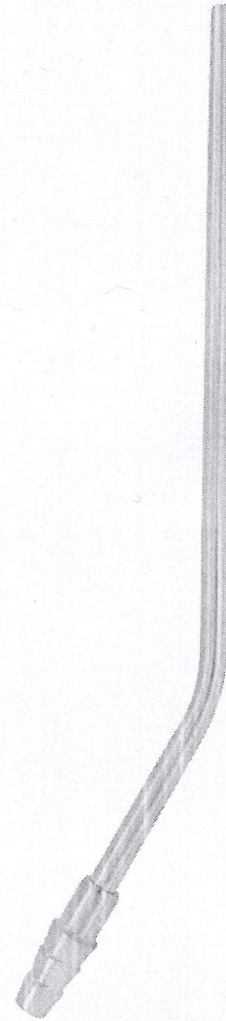
L: 110 mm

I182053	Ø 2.5 mm
 I182054	Ø 3.0 mm
I182055	Ø 4.0 mm
I182056	Ø 5.0 mm

Conique
Conical
Cónico



I182054
12 cm - 4 3/4"



I182058
13 cm - 5"

LANDANGER

Ciseaux fins - Fine scissors - Tijeras finas

MICRO

CATARACTE
CATARACT
CATARATA

Droit
Straight
Recta

B25315

Courbe
Curved
Curva

B25320



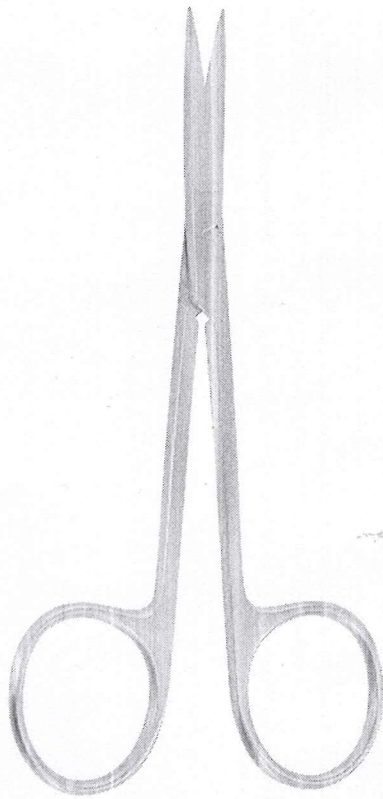
Droit
Straight
Recta

B258162

Courbe
Curved
Curva

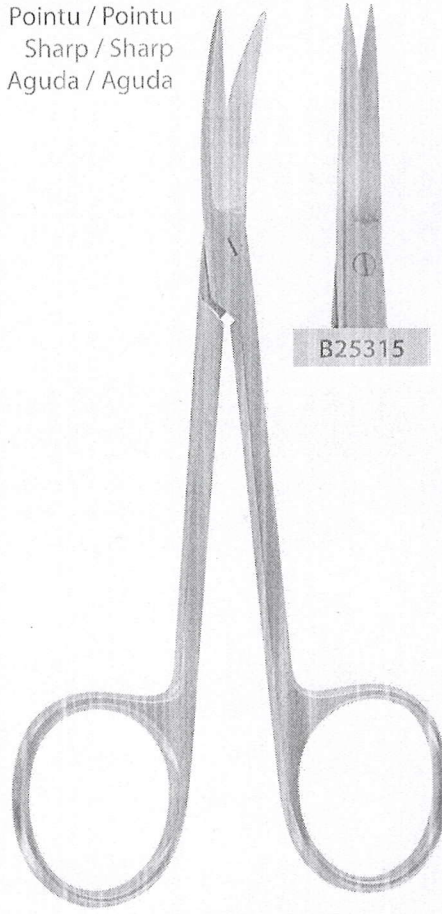
B258172

Extra plats
Extra flat
Extremadamente planas



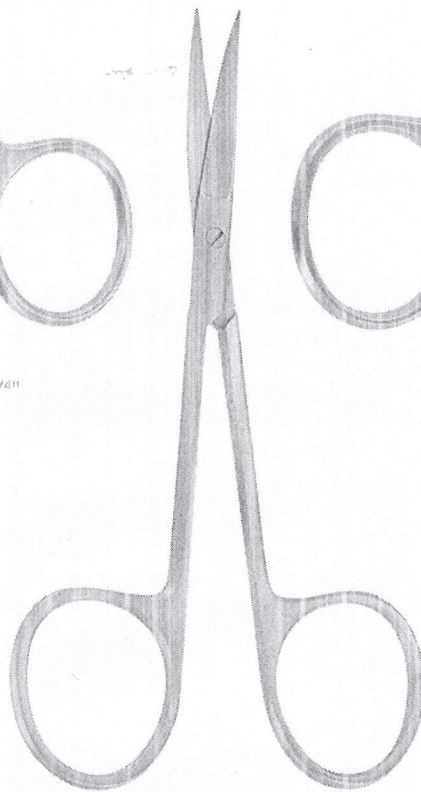
B259860
10,5 cm - 4 1/4"

Pointu / Pointu
Sharp / Sharp
Aguda / Aguda



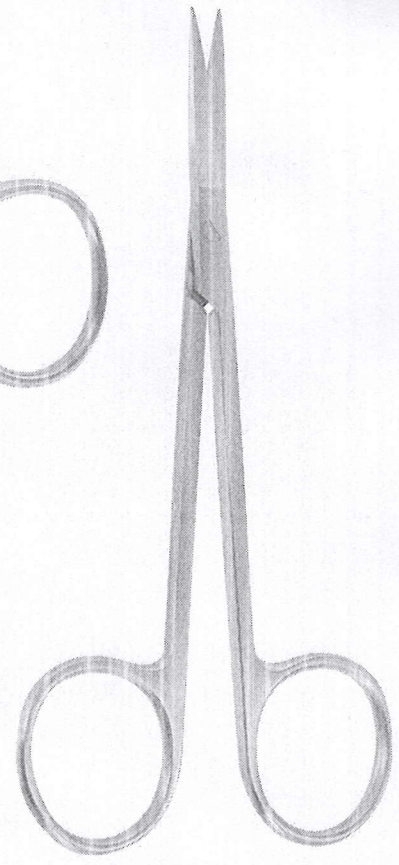
B25315

Courbe
Curved
Curva



B254805
10,5 cm - 4"

B25320
12 cm - 4 3/4"



B258162
11,5 cm - 4 1/2"