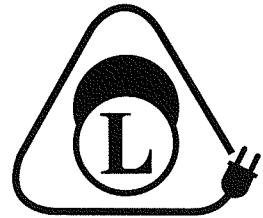


GRAND-DUCHE DE LUXEMBOURG



**Société Nationale de
Certification et d'Homologation** s.à r.l.

Notified Body

Organisme notifié - Benannte Stelle

N° 0499

EC Certificate

Certificat CE / EG Zertifikat

**Production Quality Assurance System Approval Certificate according to
Annex V of Medical Devices Directive (93/42/EEC)**

*Certificat de Système d'Assurance de la Qualité de Fabrication selon
Annexe V de la Directive relative aux Dispositifs Médicaux
(93/42/CEE)*

*Zertifikat eines Produktions-Qualitätssicherungssystems nach
Anhang V der Richtlinie über Medizinprodukt
(93/42/EWG)*

We certify that the Production Quality Assurance System of the company:
Nous certifions par la présente que le Système d'Assurance de la Qualité de Fabrication de la société:
Wir bestätigen, daß das Produktions-Qualitätssicherungssystem der Firma:

Kolplast ci Ltda

**Rua Maria Soldeira Lourençon, 691
Santa Julia - Itupeva / SP - Brazil**

is in conformity with the following requirements:

*est conforme aux exigences suivantes:
den folgenden Anforderungen entspricht:*

Annex V of Medical Devices Directive (93/42/EEC)
Annexe V de la Directive relative aux Dispositifs Médicaux (93/42/CEE)
Anhang V der Richtlinie über Medizinprodukte (93/42/EWG)

The scope of the Production Quality System is detailed in annex, which is a constituent part of this certificate.
Le domaine d'application du système d'Assurance de la Qualité de Fabrication est détaillé dans l'annexe qui est partie constituante du présent certificat.

Die Zweckbestimmung des Produktions-Qualitätssicherungssystems ist im Anhang aufgeführt und ist Bestandteil des vorliegenden Zertifikats.

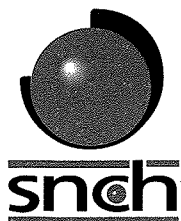
Certificate
Certificat / Zertifikat

No. 0944348-00

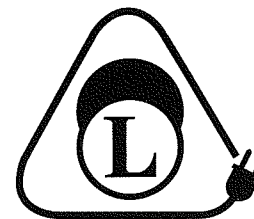
The certification is valid until 2015-05-16 and is subject to a yearly surveillance.

La certification est valide jusqu'au 2015-05-16 et est soumise à une surveillance annuelle.
Die Zertifizierung ist gültig bis zum 2015-05-16 und unterliegt einer jährlichen Überwachung.

Luxembourg, 2010-05-17



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Annex of Certificate No.

Annexe du certificat no. / Anhang zum Zertifikat Nr.

0944348-00

Kolplast ci Ltda

Scope I: Securing and maintaining sterile conditions of

*Domaine d'application I: Obtention et maintien de l'état stérile de
Zweckbestimmung I: Sterilisation und Aufrechterhaltung der Sterilität von*

Single Use Non-Active Surgical Instruments

See SNCH-marked reference list dated 2010-05-12 for details on certified types.

*Veuillez consulter la liste de références marquée SNCH et datée du 2010-05-12 pour le détail des types certifiés.
Für Details zu zertifizierten Typen siehe SNCH-gekennzeichnete Referenzliste vom 2010-05-12.*

Scope II: Aspects of manufacture concerned with the metrological requirements of

*Domaine d'application II: Aspects de la fabrication liés aux exigences métrologiques de
Zweckbestimmung II: Herstellungsschritte in Zusammenhang mit den messtechnischen Anforderungen von*

Hysterometer

This annex is only valid if attached to the certificate mentioned above.

*La présente annexe est seulement valable en relation avec le certificat mentionné ci-dessus.
Dieser Anhang hat nur Gültigkeit in Verbindung mit dem oben genannten Zertifikat.*

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Luxembourg, 2010-05-17

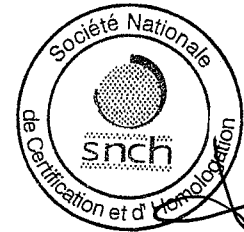


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QUALITY DEPARTMENT

List of Medical devices to be CE marked - TUV

Medical Device Generic Group incl. Software (Short description of device and indented use)	Model/variants to be CE marked
(1) Cervical Brush 18 cm long. Containing at one end a slightly cone-shaped brush with soft bristles. Used for collecting material from the uterine cervix region	1.1 Regular 1.2 Tip Protected by a resin sphere
(2) Auxiliary Forceps Two articulated valves with a sharp caldal deviation of the proximal extremity and a three-level lock. Used to hold gauze or cotton during several kinds of general medical procedures	2.1 Cheron 24,5 cm 2.2 Kelly 12 cm 2.3 Pean 25 cm
(3) Hold Cervix Forceps Two articulated straight shafts a four-level lock and aligned guide. Used to hold the uterine cervix for the introduction of Intrauterine Device	3.1 Pozzy 24,5cm 3.2 Museux 30 cm
(4) Cervix Biopsy Forceps Two articulated 30 cm shafts, a three level lock and two aligned guides. Used to perform cervix biopsy	4.1 None
(5) Anatomic Forceps 12 cm long. Used to perform several kinds of general medical procedures	5.1 Metal 5.2 Plastic
(6) Vaginal Speculum Two articulate valves which move apart as a screw is fastened. Used during the gynecologic analysis	6.1 For Virgin women 6.2 Small size 6.3 Medium size 6.4 With smoke evacuator tube 6.5 To be adapted with light source
(7) Nasal Speculum 14cm long with two small valves. Used to expose the internal surface of the nasal orifice	7.1 Adult 7.2 Infant
(8) Scissor Plastic shaft with metal blades scissors. Used to cut	8.1 Regular Scissor 8.2 Long Scissor
(9) Hysterometer 25 cm long plastic shaft with a handle, a small cylindrical stopper and a centimetre scale. Used for measuring the uterus before the introduction of Intrauterine Device	9.1 None
(10) Dermatologic Punch Plastic tube with a stainless steel rounded cutting edge tube. Used to perform skin lesions biopsy	10.1 2mm blade 10.2 3 mm blade 10.3 4 mm blade 10.4 5 mm blade 10.5 6 mm blade
(11) Dermatologic Curette Plastic shaft with a stainless steel one side shap cutting edge. Used to scratch superficial skin lesions	11.1 2mm blade 11.2 3 mm blade 11.3 4 mm blade 11.4 5 mm blade 11.5 6 mm blade



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