

ATTESTATION CE / EC CERTIFICATE

Examen de type / Type Examination

ANNEXE III de la Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX III Directive 93/42/EEC concerning medical devices

Fabricant / Manufacturer

ANIKA THERAPEUTICS S.R.L.

Via Ponte della Fabbrica 3/B

35031 ABANO TERME (PD) ITALY

Catégorie du(des) dispositif(s) / Device(s) category

Barrière mécanique pour la prévention ou la minimisation des adhésions post-chirurgicales après chirurgie abdominale et pelvienne.

Mechanical barrier for the prevention or minimization of post-surgical adhesions after surgery in the abdominal pelvic area.

Identification du(des) dispositif(s) / Identification of device(s)

HYALOBARRIER GEL - HYALOBARRIER Gel-Endo - HYALOBARRIER

(GMDN 34212)

(see addendum)

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) référencé(s) P142294, un échantillon représentatif de la production est conforme aux exigences de l'annexe I de la Directive 93/42/CEE

LNE/G-MED certifies that, on the basis of the results contained in the file(s) referenced P142294, a representative sample of the production complies with the requirements of the Directive 93/42/EEC, annex I

Début de validité / Effective date : September 2nd, 2015 (included)

Valable jusqu'au / Expiry date : October 5th, 2019 (included)



On behalf of the Certification Director

Cécile VAUGELADE

G-MED Certification Division Manager

Identification des dispositifs / Identification of devices

HYALOBARRIER Gel (ACP 200 40 mg / ml)

130012F 130011F	Box containing 3 syringes pre-filled with 10 ml of gel and 3 x 5 cm long cannulas
130003F	Box containing 1 syringe pre-filled with 10 ml of gel and 1 x 5 cm long cannula
130045F	Box containing 2 syringes pre-filled with 10 ml of gel and 1 x 5 cm long cannula

HYALOBARRIER Gel Endo (ACP 200 30 mg / ml)

130214F 130213F	Box containing 3 syringes pre-filled with 10 ml of gel and 3 x 30 cm long cannulas
130203F	Box containing 1 syringe pre-filled with 10 ml of gel and 1 x 30 cm long cannula
130209F 130210F	Box containing 2 syringes pre-filled with 10 ml of gel and 1 x 30 cm long cannula

HYALOBARRIER (ACP 200 30 mg / ml)

130100F	Box containing 3 syringes pre-filled with 10 ml of gel and 3 x 5 cm long cannulas
130110F	Box containing 3 syringes pre-filled with 10 ml of gel and 3 x 30 cm long cannulas
130120F	Box containing 1 syringe pre-filled with 10 ml of gel and 1 x 5 cm long cannula
130130F	Box containing 1 syringe pre-filled with 10 ml of gel and 1 x 30 cm long cannula
130140F	Box containing 1 syringe pre-filled with 6 ml of gel and 1 x 5 cm long cannula
130150F	Box containing 1 syringe pre-filled with 6 ml of gel and 1 x 30 cm long cannula
130160F	Box containing 1 syringe pre-filled with 3 ml of gel and 1 x 5 cm long cannula
130170F	Box containing 2 syringes pre-filled with 10 ml of gel and 1 x 5 cm long cannula
130180F	Box containing 2 syringes pre-filled with 10 ml of gel and 1 x 30 cm long cannula

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On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager

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