

TECHNICAL DATA SHEET BLUE LIFT

Endoscopic Marker







> MANUFACTURER

DERM TECH France

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> INFORMATION ABOUT THE PRODUCT

Trade name

DEEP BLUE

Endoscopic marker - 10 mL

Polyp Lifting Solution

Sodium Hyaluronate, Indigo carmine, Saline.

Indications:

Deep Blue is a transient use product which is injected into the submucosa beneath the lesion to be excised. Deep Blue is effective immediately after injection.

Following injection into the submucosa Deep Blue pushes the mucosa away from the muscularis propria (muscle) layer and enables a snare to be positioned around the base of the polyp.

The cushion of Deep Blue within the mucosa protects the underlying muscle from thermal damage, which can be caused by heat generated during the electro cauterisation of the polyp.

The viscous Deep Blue solution also acts as a tamponade, constricting blood vessels and thereby minimising bleeding from the wound. It is recommended that any marginal tissue surrounding the polyp or lesion extraction site is removed.

Reference: Product description

Packaging sizes Individual packaging:

REF BL 10 BLUE LIFT VIALS

Antibiotic glass vial, 10 mL, in a box

Packaging sizes:

Cardboard box containing 10 Vials

Order unit: Only boxes of 10 units

Storage: Controlled temperature: (0°C - 4°C) in a cool place

Confidential document

Application date: 17/03/2020 Technical data sheet - Derm Tech – DEEP BLUE



TECHNICAL DATA SHEET BLUE LIFT

Protect from direct sunlight and humidity **Shelf life**: 12 months

Class I sterile medical device – Manufactured by Derm Tech France (France) – CE marking granted by Eurofins, Notified Body no.: 0477 – Safety in use, recommendations for use (instructions for use, precautions and contraindications): refer to the information leaflet – Device not reimbursed by healthcare insurance policies.

1/2 Composition: Sodium Hyaluronate, Indigo carmine, Saline Presence of: □Yes ØNo Latex: Product of animal origin: ■Yes ☑No □Yes ⊠No PVC: Phthalate and DEHP: □Yes ⊠No Bisphenol A: ■Yes ☑No Sterility: ■No Sterile: ☑Yes Sterilisation method: Autoclave Number of uses: Single Use Storage: Storage conditions: Controlled temperature : Store at a temperature between 0°C and 4°C in a cool place, dry place protected from Direct Sunlight. Do not Freeze. Protect from direct sunlight and humidity Shelf life: 12 months Other data: **GMDN** Classification: available Bar code present: ■Yes ⊠No Reference standard used: □HIBC **☑**GS1-128 With information: ☑Yes ■No Reference: ☑Yes ■No Batch no.: Expiry date: ☑Yes □No Use:

Confidential document

Safety in use: Refer to Information Leaflet

Recommendations for use (instructions for use, precautions and contraindications): Refer to Information Leaflet



TECHNICAL DATA SHEET BLUE LIFT

Indications (CE marking intended use): Refer to Information Leaflet

Manufacturer:

Manufacturer: DERM TECH France

Country: France

CE marking

CE marking granted by Eurofins, Notified Body no.:0477 According to European directive 93/42/EEC and its amendments. Class IIa sterile medical device.