



Technical Data

Carmine Indigo 1%

ENDOSCOPIC MARKER



➤ MANUFACTURER

DERM TECH France

210 avenue Aristide Briand – 93320 Les Pavillons-sous-Bois

Tél : 01 48 02 61 63 / Fax 01 48 02 61 71

E-mails : nohaman@derm-tech.comaicha@derm-tech.com

Correspondant matériovigilance

Gérant

Tél : 01 48 02 61 63

Fax : 01 48 02 61 71

E-mails : nohaman@derm-tech.com

➤ PRODUCT INFORMATION

Commercial name :**Indigo Carmine 1%**

Indigo carmine highlights the mucosal anomalies (ulceration, fistula, irregular surface) and thus marks the tumour margins when the limits are not clearly visible.

Référence :	Sterility	Primary packaging	Secondary packaging
J2F/810160/4	Not sterile	10 ml of indigo carmine in a bottle of 10 ml	Cardboard box

Use Protocol :

The solution of indigo carmine must be sprayed on the area which needs to be examined. The operation can be repeated if necessary. If the coloration is too strong, it can be faded thanks to rinsing.

A dilution from 0.2 to 0.4 % .

Storage: Temperature above 5 ° and below 45 °,
Photosensitive product to keep away from light,
In a clean, dry place.

Shelf life: 2 years

Order unit = Minimum delivery quantity (QML): 10

Confidential document
15/09/2021

Technical sheet –Derm Tech –Indigo carmine 1%

Technical Data

Carmine Indigo 1%

ENDOSCOPIC MARKER

Class I product - Manufactured by Derm Tech France (France) - CE marking in self-certification - Safety of use, advice for use (instructions for use, precaution and contraindications): Consult the instructions.

Composition :

Indigo carmine : PPI Water , Indigotine CI 73015
 Butylene glycol / thyl Paraben / Methyl Paraben / Propyl Paraben Polysorbate 20

Contraindications :

- Hypersensitivity to indigo carmine
 - Severe high blood pressure
 - Cardiac ischemia
 - Heart insufficiency
- For allergenic patients, a trial dose must be administered before the intervention.

Contains :

Latex :	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Product of animal origin:	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Phtalate et DEHP :	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Bisphénol A :	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No



Sterility:

Sterile: J2F/810160/4 Yes No



Number of use: Single use

Storage conditions:

Conditions of conservations : Store in a controlled room temperature (5 – 45 °C), in a dry and safe light place.
 Expiration time : 2 years

Other informations :

GMDN code: Not available

Presence of a bar code :	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Repository used:	<input type="checkbox"/> HIBC	<input checked="" type="checkbox"/> GS1-128
With the information :		
Reference :	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No



Technical Data

Carmine Indigo 1%

ENDOSCOPIC MARKER

Batch number : Yes No
Expiration date : Yes No

Use :



Safety of use : Cf. Instruction for use

Directions for use (instructions for use, precaution and contraindications): Cf. Instruction for use
Indications (destination CE marking): Cf. Instruction for use

Manufacturer:

Manufacturer : Derm Tech France
Country : France

CE Mark

Product class I

Manufacturer's declaration of conformity, according to European Directive 93/42 / EEC and its amendments