



The Standard Co., Ltd.

120, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Korea
tel. 822.838.5533, fax.822.838.5523 email.kn.kim@thestd.co.kr

Product Technical Form

Designation : Submucosal Injection Agent
Trade name : Blue Eye (TS-905)

References and characteristics


Reference	Description	UNIT	PKG	MOD
1	Blue Eye	12	1	

Common name	Submucosal Injection Agent
Trade name	Blue Eye (TS-905)
GMDN code	62217
Class of the device	IIb
CE mark	Directive 93/42/EEC
Invasive medical device	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
Long term / short term	Short term
Date of first commercialization in the EU	06.06.2019

Manufacturer information

Name	The Standard Co., Ltd.
Full address	120, Gunpocheomdansaneop 2-ro, Gunpo-si, Gyeonggi-do, 15880, Korea
Unique identification number	128-86-17026
Quality certification	
Referential	ISO 13485 : 2016
Notified body	SGS Korea
EC representative (if applicable)	Name : MERIDIUS MEDICAL EUROPE LIMITED. Address : Unit 3D, North Point House, North point Business Park, New Mallow Road, CORK, Ireland Unique identification number

Description of the device

Description	Image / photo
<p>The Blue Eye (TS-905) is a specially formulated, biocompatible agent designed for inflating lesions in the GI tract. It is a solution containing highly purified sodium hyaluronic acid solution. The solution inflates lesions, so the lesions can be removed easily. Each sterilized syringe contains 5mL. The composition ratio and function of the Blue Eye's raw materials are shown below.</p>	
Kit :	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no

Components of the device and nature of the materials

a. Normal Saline	Solution
b. Sodium Hyaluronate 1Mda	Lifting Agent
c. Methylene Blue	Coloring Agent

Active substances	None
Presence of latex	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
Presence of PVC	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
Presence of phtalates and DEHP	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
Presence of Bisphenol A	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no
Presence of animal or biological origin product	<input type="checkbox"/> yes <input checked="" type="checkbox"/> no



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Field of use – Indications

Application area : Gastrointestinal Surgery

Indications : Gastrointestinal mucosal lesions or early-stage cancers

Sterilisation process

Single use	Yes
Sterile	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
Sterilisation method	Steam sterilization for solution, EO sterilization for syringe.
Sterilisation site	The Standard Co.,. Ltd.
Sterilisation test(s) carried out	Steam sterilization validation, EO sterilization validation.

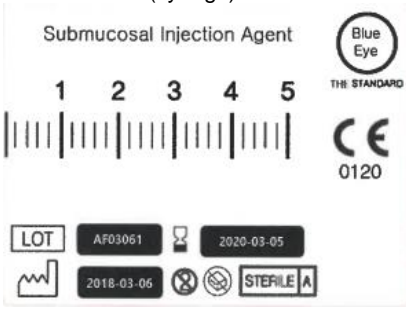


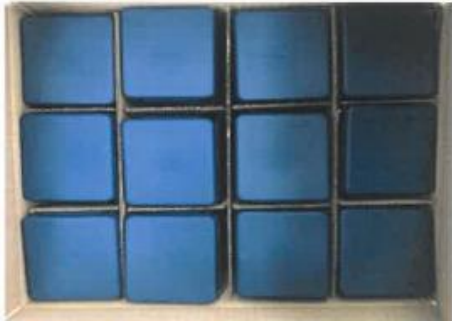
Storage conditions

Normal conservation and storage condition	Temperature : 20-26°C
Shelf life of the product	Humidity : 30-65% 2 years

Directions for use

Instructions for use	Refer to the instructions for use
Indications	Refer to the instructions for use
Precautions for use	Refer to the instructions for use
Contraindications	Refer to the instructions for use

Labelling

Individual labelling	Box
<p>Photo</p> <p>1. Label on the device (syringe)</p>  <p>2. Label on the Container</p> 	<p>Photo</p> <p>1. Label on the Canister</p>  <p>2. Carton Box</p> 



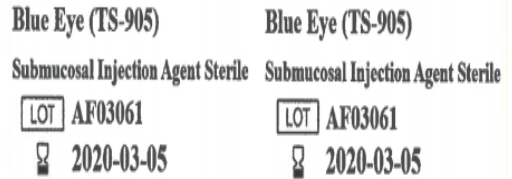
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Photo

Detachable, self-adhesive traceability stickers ---->



Packaging

Individual packaging Dimensions :			Box Dimensions :		
Material :			Material :		
	Dimensions	Material		Dimensions	Material
1. Tip Cap	Width : 10.61mm	PP	1. Canister	181 x 112 mm	PETG
2. Barrel	76.9 x 15mm	COC	2. Carton Box	495 x 375x 210mm	Paper
3. Gasket	10.2 x 12.6mm	FM257			
4. Plunger	Length : 79.6mm	GPPS			
5. Container	160 x 26.3mm	PC			

Barcode

Referential
 1. Container
 (01) 0 8809380 05020 7
 (17) 210313
 (10) LH03133

 2. Canister
 (01) 0 8809380 05078 8
 (17) 210315
 (10) LH03151

 3. Carton Box
 18809380050785

Image

1. Container



2. Canister



3. Carton Box

