

TECHNICAL CONSTRUCTION FILE

5.RAW MATERIALS

For Steri Irrigation Tip Side Open Type

Division	Department	Name	Date	Signature
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5.1 Raw materials

No.	Part Name		Materials	Weight(%)	Standard (Cas No.)
1	Cannula		Stainless Steel (STS304)	100	ISO 15510
2	HUB	White	Polypropylene (P.P)	99.6	H551 (9003-07-0)
			C.I. Pigment White 5	0.4	1345-05-7
		Yellow	Polypropylene (P.P)	99.875	H551 (9003-07-0)
			C.I. Pigment Yellow 180	0.125	77804-81-0
		Blue green	Polypropylene (P.P)	99.6	H551 (9003-07-0)
			Cupper Phthalocyanine (Pigment Blue 15)	0.3	147-14-8
			Polychloro copper phthalocyanine (Pigment Green 7)	0.1	1328-53-6
3	Primary container (Upper)		Polypropylene (P.P)	100	H551 (9003-07-0)
4	Primary container (Bottom)		Polypropylene (P.P)	100	H551 (9003-07-0)
5	Cover		Polypropylene (P.P)	100	H551 (9003-07-0)
6	Epoxy bond		Polymer Resin	100	FD-15L2

*Attachment : MSDS_ Polypropylene (P.P)

MSDS_ Stainless Steel (STS304)

MSDS_ Epoxy bond (Polymer Resin)

MSDS_ White pigment_ 1345-05-7

MSDS_ Yellow pigment_ 77804-81-0

MSDS_ Green pigment_ 1328-53-6

MSDS_ Blue pigment_ 147-14-8

5.2. ADDITIONAL MATERIAL IN PROCESS

No	Material	Standard
1	Ethylene oxide gas	ISO10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals