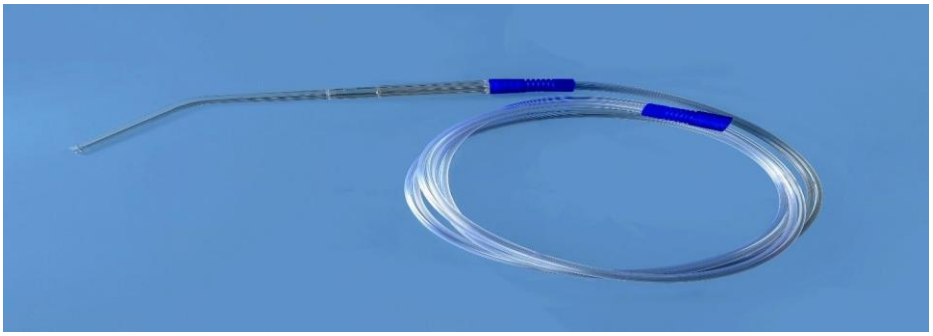


1. PRODUCT DESCRIPTION

Yankauer handle is made up of rigid plastic K-resin having crown tip or plain tip with/without thumb control and control is done by PVC sleeve. Duration of Use: Short term. Material of Composition: PVC, K-Resin.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa Rule5, medical device (classification as per EU MDR 2017/745 Annex VIII.)

3. INTENDED USE

The intended use of Yankauer handle with connecting tube is purposive for the removal of blood and fluids, suction of oral cavity and surgical field during surgery. This product is also used for suction of oropharyngeal secretions in order to prevent aspiration. A Yankauer handle set can also be used to clear operative sites during surgical procedures and its suctioned volume counted as blood loss during surgery.

4. PRODUCT CLASSIFICATION

S.N	Product	Type	GMDN Code	Classification/rule
1	**Yankauer Suction Set**	Plain tip & crown tip	38518	IIa/5

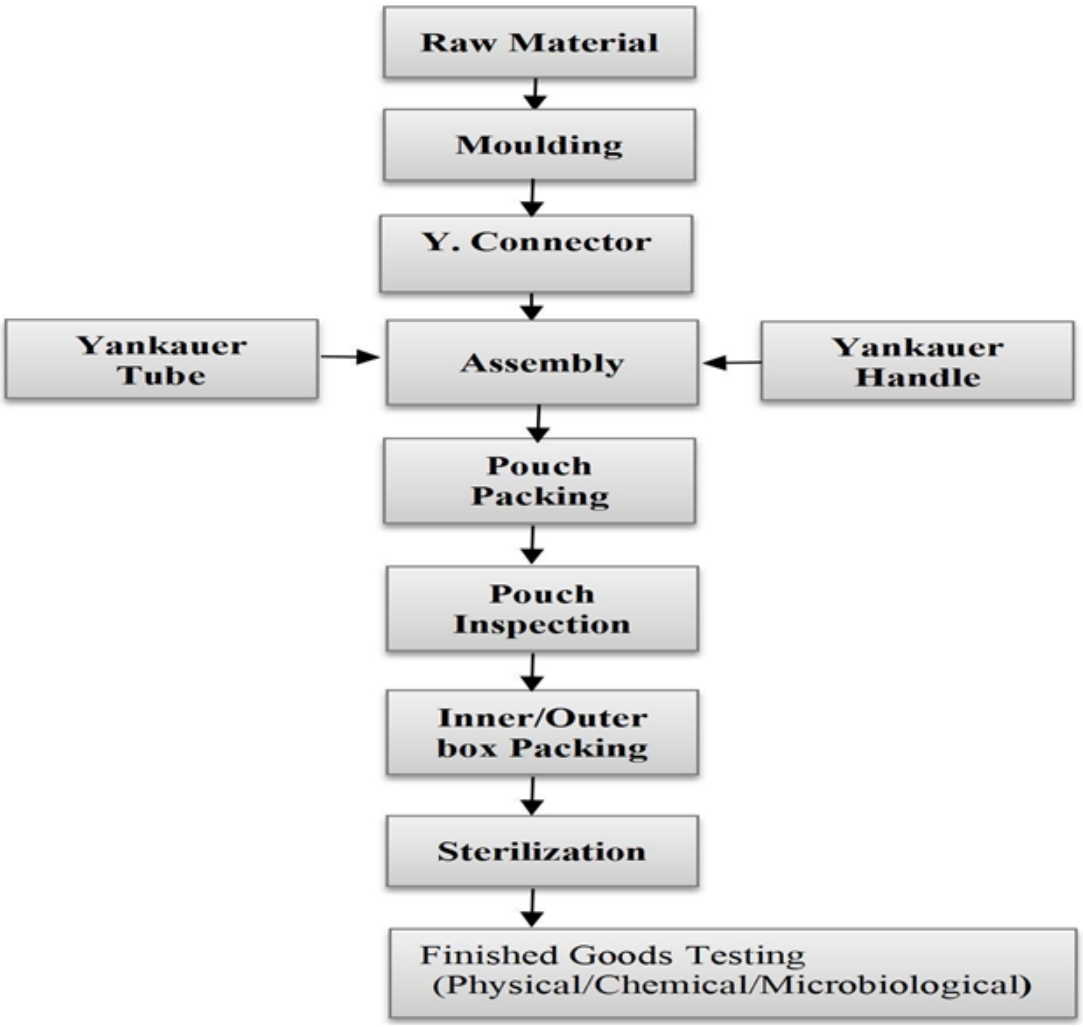
5. CONSTRUCTION MATERIAL

S. N	Component Description	Material Used
1	Yankauer Tube	PVC(Flex)
2	Yankauer Cap	PVC(Flex)
3	Yankauer Handle	K-resin
4	Sleeve	PVC

6. HARMONIZED STANDARD

S.No	Name Of Standard	ISO Std. No.
Standard for Yankauer Suction Set		
1	Medical suction equipment — Part 2: Manually powered suction equipment	ISO 10079-2:2014
2	Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source	ISO 10079-3:2014
3	6% Luer- Small-bore connectors for liquids and gases in health care applications	EN ISO 80369-7:2017
4	Sampling Procedure For Inspection By attributes	ISO 2859-1 : 1999 IS 2500-1:2000
5	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
6	Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration	EN ISO 14644-2:2015
7	Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements	EN ISO 15223-1:2021
8	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2009
9	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO 10993-3:2014
10	Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2017
10	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
11	Biological evaluation of medical devices -Part 6: Tests for local effects after implantation	EN ISO10993-6:2016
12	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
13	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2013
14	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity	EN ISO 10993-11:2018
15	Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials	EN ISO 10933-12:2012
16	Biological evaluation of medical devices- Part 17 : Establishment of allowable limits for leachable substances	EN ISO 10993-17 :2009
17	Medical devices -- Quality management systems -- Requirements for regulatory purposes	EN ISO 13485:2016
18	Medical devices – application of risk management to medical devices	EN ISO 14971:2019
19	European council directive concerning medical devices	MDD 93/42/EEC , 2007/47/EC
20	Clean rooms and associated controlled environments- bio-contamination control- general principles and methods	EN ISO 14698-1:2003
21	Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio- contamination	EN ISO 14698-2:2003

7. MANUFACTURING PROCESS



8. TECHNICAL SPECIFICATION:

1.Soft PVC tube, transparent, sterile, with longitudinal striations, torsion-resistant, internal diameter 7-8mm, proximal funnel-type connector with the possibility of cutting for connection to different types of suction units, standard distal funnel-type connector for connection to the Yankauer handle in the set, length 300cm (±10cm).
2.Yankauer handle, L-26cm (±1cm), 12 CH, transparent, sterile, with hole for digital vacuum control, distal tubular head with external diameter 4mm, standard proximal connector for connection via funnel-type connector to the suction tube.
3. An individually packaged, set"

1.Soft, transparent, sterile, longitudinally grooved, kink-resistant PVC tube, internal diameter 4-5mm, proximal funnel-type connector with cut-off possibility for connection to different types of aspirators, distal standard funnel-type connector for joining to the Yankauer handle in the set, length 300cm (±10cm).

2. One set per package. Yankauer handle, L-26cm (±1cm), transparent, sterile, with hole for digital vacuum control, distal head tube type with 4mm internal diameter. Individually packed"

9. OTHER DETAIL

Storage: Store in a cool and dry place and keep away from direct sunlight and extreme heat.

Biocompatibility: The product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.

Disposal: Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

10. COMPLIANCE INFORMATION

Manufacturer Information: Disposafe Health and Life Care Ltd.,

Plot No. 1 & 2, Sec-59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)

Drug Manufacturing License No.: MFG/MD/2019/000106
QMS Certification: EN ISO 13485:2016**,** TUV SUD Product Service GmbH
CE Marking: TUV SUD Product Service GmbH, EC Notified body No. 0123