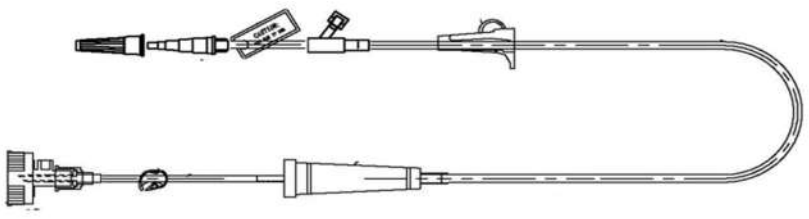
康进 KANGJIN

Tecnnical Data Sheet

1. Product Name	Enteral feeding set	
2. Description	Universal adaptor	
3. Characteristics	Gravity feeding	
4. UMDNS CODE	11677	
5. Intended use	Enteral feeding set is intended to deliver liquid nutritional formulas or water to a patient' s enteral access device (feeding tube).	
6. Instructions for use	See IFU	
7. Sizes & REF numbers	REF NO.	Product Descirption
	EN-04-2 (O)	Universal adaptor to connect to different packages of enteral nutrition: glass vials and bags

Technical Information	Component Name	Material
1. List of materials	1. Conneting adaptor	PP+ABS+PE
	2. Drip chamber	DEHP-FREE PVC
	3. Tube	DEHP-FREE PVC
	4. Regulator	ABS
	5. Warning Label	Paper
	6. Connector	ABS
	7. Protective cap	PP
2. Latex free	Yes	
3. PHT/DEHP free	Yes	
4. Shelf life	3 years	
5. Sterilization method	Sterilized using Ethylene Oxide	
6. Packaging specification	REF NO.	Details
	1200-EN-04-2 (O)	30pcs/CTN
7. Technical Drawing		

Quality & Regulatory Information

1. Quality certificate	**Quality Management Syestem according to ISO13485**		
2. Product Classification	**Class I in sterile condition accoridng to Annex V of MDD 93/42ECC**		
3. List of Standards	**The product is compliant with the following standards and regulations:**		
	Document reference	**Titile**	
	ISO 20695:2020	Enteral feeding systems — Design and testing	
	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	
	EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization	
	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	
	EN ISO 11135:2014+A1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	
	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	
	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	
	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices	
	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	
	EN 1041:2016	Information supplied by the manufacturer of medical devices	
REV	**01**		**Date: 2023/04/05**