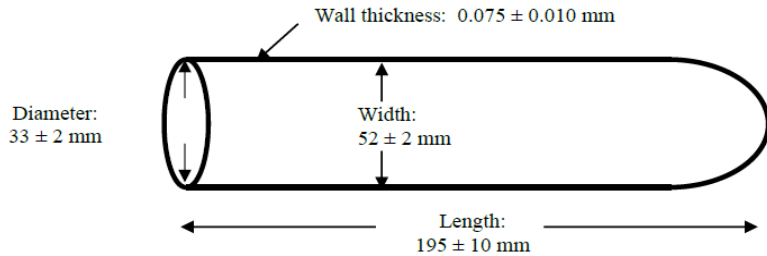


Common Technical Information Sheet

Technical Dossier - Sterile & Non-sterile Natural Rubber Latex Protective Transducer Covers		
1	Contract Manufacturer information	
1.1	Contract Manufacturer name	Karex Industries Sdn. Bhd.
1.2	Contract Manufacturer address	PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.
2	Device identification	The GMDN Code of Non-sterile and Sterile Natural Rubber Latex Protective Transducer Covers is 60608 (Body-orifice ultrasound imaging transducer cover, basic)
3	Product Description	
3.1	Family Name	Sterile & Non-sterile Natural Rubber Latex Protective Transducer Covers
3.2	Product Code	KX07
3.3	Device Diagrams	KX07 Unlubricated Probe Cover  The diagram illustrates the KX07 Unlubricated Probe Cover, which is a cylindrical device with a rounded distal end. The dimensions are as follows: Diameter: 33 ± 2 mm Width: 52 ± 2 mm Length: 195 ± 10 mm Wall thickness: 0.075 ± 0.010 mm
3.4	Product Characteristic	Sterile & Non-sterile Natural Rubber Latex Protective Transducer Covers are used on diagnostic probes to help minimize cross contamination. It is made of natural rubber latex, a thin, conformal covering to fit various and specific ultrasound transducer shapes. The cover is made by dipping to form a general cylindrical shape. It is closed at the proximal end and opens at the distal end for insertion of the ultrasound transducer. The surface of the transducer cover shall be smooth throughout and it is packed in a rolled-up form. It could be packed either lubricated or unlubricated.

3.5	Warnings/ Safety Precautions	• For maximum benefit, carefully follow the instructions inside this package. • Before use, you should be trained in ultrasonography. • DISPOSE of single use components as infectious waste. • Transducer cover are for single use only, DO NOT REUSE transducer covers. Reuse or reprocessing may create a risk of contamination of the device and cause patient infection or cross-infection. • USE ONLY WATER BASED LUBRICANT, avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the cover. • Disinfection of the transducer probe after each examination could reduce the probability of cross-contamination. • Report any serious incident occurred from using the device to the manufacturer and the relevant national competent authority. Additional Warnings for Sterile Transducer Covers •DO NOT USE the transducer covers if the individual package is obviously damaged. Discard that covers and use a new one from an undamaged package.
3.6	Instruction for Use	For Non-sterile covers: • Carefully tear off the foil pack. Make sure not to damage the cover. • During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc. • Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover. • Inspect the cover to ensure no holes or tears. For Sterile covers: • Carefully tear off the foil pack at the location where the package can be opened (Symbol: ▲ Open here). Make sure not to damage the cover. • Remove the cover using proper sterile technique. During removal from foil, avoid damage to the cover by sharp edges, fingernails and etc. • Place the cover over the transducer. Pull cover tightly over the transducer to remove wrinkles and air bubbles, taking care to avoid puncturing the cover. • Inspect the cover to ensure no holes or tears.
3.7	Principles of Operation	Principles of operation can be defined as how the user interacts with the device.
3.8	Mode of Action	when the transducer cover is used during invasive medical examinations, it acts as a barrier between the transducer probe and the mucous membrane
3.9	Shelf Life	5 years.
4	Storage	Store in a cool dry place, away from direct sunlight.
5	Intended Use	For barrier protection during invasive medical examination and diagnosis using transducer probe.
6	Intended User	The device is intended to be used by healthcare provider trained in the use of ultrasound.
7	Medical or Clinical Claims	Prevention of cross-contamination
8	Medical or Clinical Benefits	Prevent cross-contamination of probes and consequently reduce the risk of cross infection in patients undergo invasive ultrasound examinations and diagnoses (i.e transvaginal and transrectal scan)
9	Medical or Clinical Conditions	Cross-contamination of transducer probe

10	Patient population, targeted population	Adult male or female, Healthcare provider.
11	Body parts in contact with the device	Mucosal membrane, (e.g., vagina and rectum) and intact skin.
12	Repeat applications/Single use/Single patient use	Single use.
13	Invasive/implantable/injured or intact skin	Mucosal membranes.
14	Duration of use/ Contact duration categorization	Short term use, continuous use between 60 minutes and 30 days.
15	Lifetime of the device	The period of invasive medical examinations and diagnosis using transducer probe
16	Contraindications	This product contains natural rubber latex which may cause allergic reactions
17	Technical Standards and Common Specifications	No specific Technical Standards and Common Specifications available for Natural Rubber Latex Protective Transducer Covers. However, "ISO 4074 / EN ISO 4074 Natural Latex Rubber Condoms – Requirements and Test Methods" is used as standard for transducer covers
18	Pre-Clinical Evaluation Report	K-TF-03_Appendix 12_Biocompatibility Test Reports_Cytotoxicity_Sterile NRL Covers K-TF-03_Appendix 12_Biocompatibility Test Reports_Sensitization_Sterile NRL Covers K-TF-03_Appendix 12_Biocompatibility Test Reports_Systemic Toxicity_Sterile NRL Covers K-TF-03_Appendix 12_Biocompatibility Test Reports_Vaginal Irritation_Sterile NRL Covers

List of applied / harmonized standards and Common Specification

No.	Reference No.	Title
1	ISO 13485:2016/ EN ISO 13485:2016 +A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.
2	ISO 4074:2015/EN ISO 4074:2015	Natural rubber latex male condoms -- Requirements and test methods
3	ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
4	ISO 10993-5:2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity.
5	ISO 10993-10:2021	Biological evaluation of medical devices. Tests for skin sensitization.
6	ISO 10993-11:2017	Biological evaluation of medical devices. Tests for Systemic Toxicity
7	ISO 10993-18:2020	Biological evaluation of Medical Device - Part 18: Chemical characterization of materials
8	ISO 10993-23:2021	Biological evaluation of Medical Device - Part 23: Tests for irritation
9	ISO 14971:2019/EN ISO 14971:2019 + A11:2021	Medical devices – Application of risk management to medical devices
10	ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
11	NFS 97-034:2007	Additional lubricants and other medicinal or non-medicinal preparations intended or likely to be put in contact with natural rubber latex condoms – Compatibility -Specifications and test methods.
12	ASTM D7661-23	Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms

13	ISO 29941:2010	Condoms - Determination of nitrosamines migrating from natural rubber latex condoms
14	ISO 2859-1:1999	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
15	ASTM D4169-23	Standard Practice for Performance Testing of Shipping Containers and Systems
16	USP 61	Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
17	USP 62	Microbiological Examination of Nonsterile Products: Test for Specified Microorganisms
18	Version 1.22 dated 05-2019	Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices
19	MEDDEV 2.5/9 Rev 1 (February 2004)	Implications of The Medical Devices Directives (93/42/EEC) in Relation to Medical Devices Containing Natural Rubber Latex, A Guide for Manufacturers and Notified Bodies
20	MEDDEV 2.7/1 Rev 4 (June 2016)	Clinical evaluation: Guide for manufacturers and notified bodies
21	EN ISO 11607-1: 2020	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.
22	EN ISO 11607-2: 2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
23	ISO 11737-1: 2018/EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products.
24	ISO 11737-2: 2019/ EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.
25	ISO 11137-1: 2006/EN ISO 11137-1:2006	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
26	ISO 11137-2: 2013	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose.
27	ISO 11137-3: 2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control.
28	MDCG 2020-6 (April 2020)	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC.A guide for manufacturers and notified bodies
29	MDCG 2020-7 (April 2020)	Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies
30	MDCG 2020-8 (April 2020)	Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies
31	ASTM F1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
32	EN 868-5:2018 (Annex E)	Method for the Determination of Peel Characteristics of Paper/Plastic Laminate Products
33	ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
34	ASTM D3078-02(2021)	Standard Test Method for Determination of Leaks in Flexible packaging by bubble emissions
35	ASTM F88-21	Standard Test Method for Seal Strength of Flexible Barrier Materials

Relevant tests and studies

1	Biocompatibility	Biological Evaluation tests were carried out based on the recommended tests outlined in ISO 10993-1 and risk analysis of the devices.
2	Lubricant Compatibility Studies	Compatibility study between the ultrasound gel and Natural Rubber Latex Male Transducer Covers was carried out in accordance to NFS 97-034 standards.

3	Microbial Content	Test is conducted in accordance to the sampling plan and frequency stipulated in K-QP-03
4	Package Performance Studies	The tests were carried in accordance with international standard ASTM D4169 (Distribution Cycle 13, Quality Assurance Level II).
5	Phthalates & PAH Test Reports	Phthalates & PAH content of the covers have been tested. Results showed that the covers does not contain phthalates & PAH.
6	Nitrosamine Test Reports	Nitrosamine content of the covers is monitored at yearly intervals.
7	Protein Contents	Protein contents on the covers is monitored at fixed intervals to ensure consistency of the cover performance.
8	Shelf Life and Stability Reports	Shelf life of cover is established as 5 years.
9	Clinical Evidence	A compilation of scientific literature relating to the safety, performance, design characteristics and intended purpose of the device is outlined in Clinical Evaluation Report.

Method of sterilization process		
1	Microbiological Validation	Minimum irradiation dose and sterilization dose validation has been conducted in accordance with ISO 11137. Effect of maximum dose of gamma radiation on the covers was also studied. Details of the validation is appended in Appendix 13. Methods of controlling the sterilization by both the sterilizer and KISB are appended in Appendix 14.

