KAREX INDUSTRIES SDN. BHD.

Title	DECLARATION OF CONFORMITY FOR STERILE OR NON-STERILE NATURAL RUBBER LATEX PROTECTIVE TRANSDUCER COVERS	Doc. No. K-DOC–083	
		Issue No. 01	
Date	8th October 2021	Page	1 of 2

European Communities Council Directive 93/42/EEC Concerning Medical Devices.

(including the revisions from Directive 2007/47/EC.)

This declaration of conformity is issued under the sole responsibility of Karex Industries Sdn. Bhd.

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Sterile or Non-Sterile Natural Rubber Latex Protective Transducer Covers
Manufacturer:	Karex Industries Sdn. Bhd. PTD 7906 & 7907, Taman Pontian Jaya, Batu 34, Jalan Johor, 82000 Pontian, Johor Darul Takzim, Malaysia.
Trade Name:	As shown in Annex I
Intended Use:	For barrier protection during invasive medical examination and diagnosis using transducer probe.
Standards tested to:	In-house Specifications
MDD Directive Classification No. & Rule:	Class IIa, Rule 5.
GMDN Code:	60608 (Body-orifice ultrasound imaging transducer cover, basic, sterile) 60609 (Body-orifice ultrasound imaging transducer cover, basic, nonsterile)
Notified Body:	TUV SUD Product Service GmbH (0123) Zertifizierstelle Ridlerstraβe 65, 80339 MÜNCHEN, Germany
EU Authorised Representative:	Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment route:	Annex V
EC Certificate Number:	G2 102558 0003 Rev.01

Signed .....

Tee Poh Suan
Senior Group RA Manager
Port Klang, Selangor, Malaysia

KAREX INDUSTRIES SDN. BHD. 170363-X

Date 08.10.2021

Who is the legal person with responsibility for the design, manufacture, packaging and labelling of the device that is placed on the market under the name of Karex Industries Sdn. Bhd. regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

KAREX INDUSTRIES SDN. BHD.

Title	DECLARATION OF CONFORMITY FOR STERILE OR NON-STERILE NATURAL RUBBER LATEX PROTECTIVE TRANSDUCER COVERS	Doc. No. K-DOC–083	
		Issue No. 01	
Date	8th October 2021	Page	2 of 2

ANNEX I - Product listing

Brand Name	Model No.	Types	Distributor Name	Description	Medline REF
Sterile					
Medline	KX06	Sterile, Unlubricated	Medline International France S.A.S	Diameter: 28mm ± 1.5mm Length: 295mm ± 10mm	ICE28295L
	KX07	Sterile, Unlubricated		Diameter: 33mm ± 1.5mm Length: 195mm ± 4mm	ICE33230L
Non-Sterile					
Medline	KX06	Non-sterile, Unlubricated	Medline International France S.A.S	Diameter: 28mm ± 1.5mm Length: 295mm ± 10mm	NS-ICE28295L
	KX07	Non-sterile, Unlubricated		Diameter: 33mm ± 1.5mm Length: 195mm ± 4mm	NS-ICE33230L
	KX07	Non-sterile, Lubricated		Diameter: 33mm ± 1.5mm Length: 195mm ± 4mm	NS-ICE33230LL