



KAREX INDUSTRIES SDN. BHD.

Title	DECLARATION OF CONFORMITY FOR NON-STERILE NATURAL RUBBER LATEX PROTECTIVE TRANSDUCER COVERS	Doc. No. K-DOC-074
		Issue No. 00
Date	26 th May 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: 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: 60609 (Body-orifice ultrasound imaging transducer cover, basic, nonsterile)

Notified Body: TUV SUD Product Service GmbH (0123)
Zertifizierstelle Ridlerstraße 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



Date 26.05.2021

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.



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ANNEX I - Product listing

Brand Name	Model No.	Types	Distributor Name	Description
-	KX07	Non-Sterile, Unlubricated	Vulkan Medical A.S.	Width: 52mm ± 2mm Length: 195mm ± 4mm Diameter: 33mm ± 1.5mm