KAREX INDUSTRIES SDN. BHD.

(Reg.No. : 170363-X)

EC DECLARATION OF CONFORMITY

Legal Manufacturer's Name	: KAREX INDUSTRIES SDN. BHD.
Legal Manufacturer's Address	: PTD 7906 & 7907, Taman Pontian Jaya, Bt 34 Jalan Johor, Pontian, 82000 Johor, Malaysia.
CE Notified Body No. of Manufacturer	: 0120
Name of Certified Body of Manufacturer	: SGS United Kingdom System and Services Certification 202B Worle Parkway, Weston-super-Mare, BS22 6WA, United Kingdom.
Approval Certificate No. of Manufacturer	: MY99/00528
EC Representative of Manufacturer	: Advena Ltd. Pure Offices, Plato Close, Warwick CV34 6WE UK

List Number and Size Code of Device	**Name & Description of Device**	**Annex**
Class IIa	Vaginal Rectal (KX11) 144pcs &	V
	Lumbar Abdominal (KX12) 144pcs	

We hereby declare that the qualitative and quantitative products described above and bearing the CE Marking are in conformity with the relevant provisions of the Council Directive 93/42/EEC of 14 June 1993 as amended by the Directive 2007/47/EEC concerning medical devices.

The Manufacturer and Notified Body will preserve all the supporting documents.

If the technical files or the applicable standards of the products change, our Company will promptly declare the changes and ensure that the Notified Body and the authorized European Representative receive the related documents.

Signature :

KAREX INDUSTRIES SDN BHD. QUALITY ASSURANCE

Full Name : Mary Goh Yin
Position : Quality Assurance Director
Date : 4th July 2015

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Cert No : MY99/51086 Cert No : MY99/51085