UK Declaration of Conformity

UKCA Marking & UK MDR 2002 Compliance

This UK declaration of conformity is issued under the sole responsibility of Kenex (Electro-Medical) Limited, the manufacturer of the below listed UKCA marked medical devices. The requirements specified in Regulation UK MDR 2002 regarding medical devices have been fulfilled in relation to the listed device groups.

Electrical devices are also in conformity with UK Regulation 2012/3032 as amended ("the RoHS Regulations"), on the restriction of the use of certain hazardous substances in electrical and electronic equipment, UK Regulation 2023/722 REACH (Amendment) Regulations 2023.

The listed products which have been classified as Class 1 under MDD 93/42 EEC consolidated 2007/47/EC Annex IX, Rule 1, (Rule 12 LED Lights) are manufactured in conformity with technical documentation as per Annex VII, Section 3 and meet the directives and standards that apply to them.

The declared medical devices comply where appropriate, with the following European standards: BS EN 60601-1:2006+A2:2021, BS EN 61331-1:2014, and BS EN 61331-2:2014 BE EN ISO 14971:2019, BS EN ISO 15223-1:2021. Kenex is certified as meeting quality management systems in accordance with standard BS EN ISO 13485:2016+A11:2021. The quality management system is audited by our UK Approved Body SGS UK Limited.

Intended purpose of radiation shields:
Used during diagnostic x-ray medicine to protect patients and healthcare personnel from unnecessary exposure to primary or scattered x-rays.
Classification: Class I medical devices.

Kenex radiation shields, mobile, including: -
Model groups 303, 310, 314, 326 and 317
Global Model Number (GMN) Basic UDI-DI: 50554494SHMXK
Global Medical Device Nomenclature (GMDN) 38373

Kenex radiation shields, table mounted, including: -
Model groups 311/DS, 311/TC, 312/DS, 312/E, 313/A2 and 313/A3
Global Model Number (GMN) Basic UDI-DI: 50554494SHTXZ
Global Medical Device Nomenclature (GMDN) 38375

Kenex radiation shields, overhead suspended (with or without lights), including: -
Classification: Class 1 Active medical device with LED Lights or Class 1 medical device without lights
Model groups 300, 308, 350, 351, 354, ceiling tracks 3001
Global Model Number (GMN) Basic UDI-DI: 50554494SHOXP
Global Medical Device Nomenclature (GMDN) 38374

Intended purpose of pendent systems:
Designed to support an image display monitor, equipment controls consoles or tailored to suit specific requirements.
Classification: Class I medical device.

Kenex pendent systems for monitors & controls: -
Model groups 333
Global Model Number (GMN) Basic UDI-DI: 50554494PDOWU
Global Medical Device Nomenclature (GMDN) 32245

Intended purpose of medical lighting:
Used to illuminate the patient's body
Classification: Active Class I medical devices.

Kenex lights, overhead examination/treatment, including: -
Model groups LED 130F, LED 150F, LED 150FP and LED 150MC
Global Model Number (GMN) Basic UDI-DI: 50554494LIMWK
Global Medical Device Nomenclature (GMDN) 12276

Kenex lights, overhead operating, including: -
Model groups LED 6MC and LED 300DF SC
Global Model Number (GMN) Basic UDI-DI: 50554494LIOWP
Global Medical Device Nomenclature (GMDN) 12282

Intended purpose of mobile holders:
Used to position and hold an image receptor (x-ray film cassette or flat panel digital detector).
Classification: Class I medical devices.

Kenex mobile holders for portable flat panel detectors and cassettes, including: -
Models 1305/3/1, 1305/8/1, 1330/3, 1330/4, 1330/4/1, 1330/5 and 1350/1
Global Model Number (GMN) Basic UDI-DI: 50554494CH9H
Global Medical Device Nomenclature (GMDN) 14473

Intended purpose of imaging chairs:
Designed to support and position a seated patient during examinations involving the use of diagnostic x-ray systems.
Classification: Class I medical device.

Kenex imaging chair: -
Model 1501/D
Global Model Number (GMN) Basic UDI-DI: 50554494CHXVR
Global Medical Device Nomenclature (GMDN) 40697

Intended purpose of storage racks:
Used to hold or store equipment between use or to preserve the inherent shielding capabilities of radiation protective articles.
Classification: Class I medical devices.

Kenex storage racks for radiation shielding articles/equipment controls, including: -
Model groups 100, 102/C, 103, 312/W, 313/A3/W, 1340 and 1342
Global Model Number (GMN) Basic UDI-DI: 50554494AR9X
Global Medical Device Nomenclature (GMDN) 38368

Intended purpose of sandbags:
Positioning aids (sandbags) are used to facilitate adequate positioning and immobilization of a patient's body parts during diagnostic imaging procedures.
Classification: Class I Medical device.

Kenex patient positioning aids (sandbags), including: -
Model groups 1701/02, 1701/02/H, 1701/06, 1701/06/H, 1701/07, 1701/07/H, 1701/08, 1701/08/H, 1701/09, 1701/09/H, 1701/10, 1701/10/H, 1701/15, 1701/15/H, 1701/18, 1701/18/H, 1701/28, 1701/28/H, 1701/29, 1701/29/H
Global Model Number (GMN) Basic UDI-DI: 50554494SBPX7
Global Medical Device Nomenclature (GMDN) 61131

MHRA Reference Number 6841

Signed:

Paul Robinson
Quality & Regulatory Affairs Manager
On behalf of Kenex (Electro-Medical) Limited
Place: Harlow, CM19 5QB, UK
Date: 25/07/2024

UK CA

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