EU Declaration of Conformity

CE Certification MDR 2017/745

This EU declaration of conformity is issued under the sole responsibility of Kenex (Electro-Medical) Limited, the manufacturer of the below listed CE marked medical devices. The requirements specified in EU Regulation 2017/745 (MDR) regarding medical devices have been fulfilled in relation to the listed device groups. The devices are also in conformity with EU Directive 2011/65/EU, as amended by Directive 2015/863 (RoHS 3), on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The declared medical devices comply where appropriate, with the following European standards: EN 1021-1, EN 1021-2, EN 50601-1-2, EN 60601-1, EN 60601-2-41, EN 61331-1:2014, and EN 61331-2:2014. Kenex is certified as meeting quality management systems in accordance with standards ISO 13485:2016 and ISO 9001:2015. QA systems are audited by 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, (respectively > 1mm lead & 0.5mm Pb equivalent).
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

Kenex radiation shields, overhead suspended (with or without lights) including: -
Model groups 300, 308, 350, 351, 354, ceiling tracks 3001
Global Model Number (GMN) Basic UDI-DI: 50554494SHOXP

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

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

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,
Global Model Number (GMN) Basic UDI-DI: 50554494LIMWK

Kenex lights, overhead operating including: -
Model groups LED 2SC, LED 2MC, LED 3SC, LED 3MC and LED 300DF
Global Model Number (GMN) Basic UDI-DI: 50554494LIOWP

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

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

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

EC REP

EC authorised representative: Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, The Netherlands.

Single Registration Number (SRN): GB-MF-000009022

Signed:

Paul Hunt
Managing Director
On behalf of Kenex (Electro-Medical) Limited
Place: Harlow, CM19 5QB, UK
Date: 15/09/2021

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