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.

As outlined in Annex VI Medical Device Regulation (EU) 2017/745 of the Official Journal of the European Communities, the conformity assessment procedure performed, is as per Annex IX chapter I and III for review of the Quality Management system and technical documentation.

Kenex (Electro-Medical) Limited declare that the listed products have been classified as Class 1 under Annex VIII, Chapter III, Rule 1, (Class 1 Active under Annex VIII, Chapter III Rule 13 LED Lights) and are manufactured in conformity with technical documentation under Annex II, III and meet the directives and standards that apply to them.

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, REACH directive EC 1907/2006.

The declared medical devices comply where appropriate, with the following European standards: BS EN 60601-1:2006+A2:2021, BS EN 61331-1:2014, 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 notified body SGS Limited.

Intended purpose of radiation shields:
Used during diagnostic x-ray medicine to protect patients and healthcare personnel from unintentional 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
GMDN: 38373
EMDN: T0399

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
GMDN: 38375
EMDN: Z11030503

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
GMDN: 38374
EMDN: T0399

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
GMDN: 32245
EMDN: V9099

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
GMDN: 12276
EMDN: Z12010701

Kenex lights, overhead operating, including: -
Model groups LED 6MC and LED 300DF SC
Global Model Number (GMN) Basic UDI-DI: 50554494LIOWP
GMDN: 12282
EMDN: Z12010701

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
GMDN: 14473
EMDN: Z11030501

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
GMDN: 40697
EMDN: V080299

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: Accessories to 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
GMDN: 38368
EMDN: N/A

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
GMDN: 61131
EMDN: Z12011299

EC REP

EC authorised representative: Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands.
Emergo Single Registration Number (SRN): NL-AR-000000116

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

CH REP

Swiss authorised representative: MedEnvoy Switzerland, Gotthardstrasse 28, 6302 Zug, Switzerland.

Signed:

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

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