



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

EC REP

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

CH REP

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

Kenex 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: 25/03/2024



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