



# 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 class I 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 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.

EU authorised representative: Sensus Consulting EU, The Black Church, St Mary's Place, Dublin 7, D07 P4AX. Ireland.

**Kenex radiation shields, mobile including: -**

Model groups 303, 310, 314, 326 and 317  
Global Model Number (GMN) Basic UDI-DI: 50554494SHMXX  
GMDN: 38373

**Kenex radiation shields, overhead suspended (with or without lights) including: -**

Model groups 308, 350, 351, 354, ceiling tracks 3001  
Global Model Number (GMN) Basic UDI-DI: 50554494SHOXP  
GMDN: 38374

**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

**Kenex pendent systems for shields, monitors & controls: -**

Model groups 333  
Global Model Number (GMN) Basic UDI-DI: 50554494PDOWU  
GMDN: 32245

**Kenex lights, mobile overhead examination / treatment including: -**

Model groups LED 130F, LED 150F, 2SC and 3SC  
Global Model Number (GMN) Basic UDI-DI: 50554494LIMWK  
GMDN: 36843

**Kenex lights, overhead examination including: -**

Model groups LED 130F and LED 150F  
Global Model Number (GMN) Basic UDI-DI: 50554494LIEOP7  
GMDN: 12276

**Kenex lights, overhead operating including: -**

Model groups LED 2SC, 2MC, 3SC, 3MC and 300DF  
Global Model Number (GMN) Basic UDI-DI: 50554494LIOWP  
GMDN: 12282

**Kenex mobile holders for portable flat panel detectors and cassettes including: -**

Models 1305/3/1, 1305/8/1, 1330/3, 1330/4, 1330/5 and 1350/1  
Global Model Number (GMN) Basic UDI-DI: 50554494CH9H  
GMDN: 14473

**Kenex imaging chair: -**

Model 1501/D  
Global Model Number (GMN) Basic UDI-DI: 50554494CHXVR  
GMDN: 40697

**Kenex storage racks for radiation shields and aprons, including: -**

Model groups 100, 102/C, 103, 312/W, 313/A3/W and 1342  
Global Model Number (GMN) Basic UDI-DI: 50554494AR9X  
GMDN: 38368

**Kenex radiographic markers, including: -**

Model 1206  
Global Model Number (GMN) Basic UDI-DI: 50554494MKAM  
GMDN: 40805

Signed:



Paul Hunt  
Managing Director  
On behalf of Kenex (Electro-Medical) Limited  
Date: 11/03/2020



**CE** 2017/745

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