EU Declaration of Conformity

CE Certification PPE 2016/425

This EU Declaration of Conformity is issued under the sole responsibility of Kenex (Electro-Medical) Limited, the manufacturer of the below listed category III products. The requirements specified in EU Regulation 2016/425 (PPE) relating to personal protection against external ionising radiation equipment, have been fulfilled.

The listed products are in conformity with harmonised standards BS EN 61331-1 relating to the x-ray attenuating properties of flexible materials used, and to BS EN 61331-3 relating to x-ray protective clothing, and to BS EN 13402-3 & BS EN ISO 13688 relating to the attributes of protective clothing.

Kenex (Electro-Medical) Limited is certified as meeting the requirements of ISO 13485, and EN ISO 13485 related to medical devices quality management systems and is additionally certified to ISO 9001. Module B EU type-examination certificate F120/967318 and Module D conformity assessment certificate F120/967474 are issued SGS Fimko Oy. QA systems are audited by SGS UK Limited.

The required conformity assessment procedure was under the surveillance of notified body: SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki Finland. Notified body identification number: CE 0598.

Kenex LytaType x-ray protective clothing including: -
model groups 903, 905, 907, 909, 910, 911, 915, 917, 919, 921, 951 and 953
Global Model Number (GMN) Basic UDI-DI: 50554494AXAB

EC REP

EC authorised representative: Emergo Europe, Prinsessegracht 20, 2514 AP The Hague, 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: 18/07/2022

CE 0598

Kenex (Electro-Medical) Limited
Unit 17, RO24 Greenway, Harlow Business Park, Harlow, Essex CM19 5QB, England
T: +44 (0)1279 417241 F: +44 (0)1279 443749 E: kenex@kenex.co.uk www.kenex.co.uk