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 61331-1:2014 relating to the x-ray attenuating properties of flexible materials used, and to BS EN 61331-3:2014 relating to x-ray protective clothing, and to BS EN 13402-3:2013 & BS EN ISO 13688:2013 relating to the attributes of protective clothing.

Kenex (Electro-Medical) Limited is certified as meeting the requirements of ISO 13485:2016, and EN ISO 13485:2016 related to medical devices quality management systems and is additionally certified to ISO 9001:2015. QA systems are audited by SGS UK Limited.

Module B EU type-examination certificate F120/967318 and Module D conformity assessment certificate F120/967474 are issued SGS Fimko Oy.

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

EU authorised representative: Emergo Europe B.V., 2514 AP The Hague, The Netherlands.

Signed:

Paul Hunt
Managing Director
On behalf of Kenex (Electro-Medical) Limited
Place: Harlow, CM19 5QB, UK
Date: 18/12/2020

CE 0598

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