NELSONX srl

USER INFORMATION
X-ray Personal Protective Equipment

CE 2895

Please read carefully the following information.
These user information have been registered by SHIRLEY Testing & Certification DUBLIN IRL n° 2895 Notified Body

REFERENCE : PPE Regulation (EU) 2016/425
STANDARD EN IEC 61331-3 : 2014 CAT. III
STANDARD EN IEC 61331-1 : 2014
STANDARD EN 13402-3:2017
STANDARD EN 13688:2022

RISK ASSESMENT : The PPE is intended to protect from " **ionizing radiation** " CATEGORY III- letter D - Annex 1 of PPE Regulation (EU) 2016/425

USE : protective clothing against diagnostic medical X-radiation. The devices may be used together, according to specific need, i.e. apron with collar or jacket with gown etc.
The PPE satisfy the **Essential Health and Safety Requirements** by the specific Standard applied to protective clothing against external x-radiation EN IEC 61331-3 : 2014 and the general PPE Regulation (EU) 2016/425
The level of protection has to be stated by the Doctor, taking account of the diagnostic and clinical necessities, according to the organ to be examined on the basis of technical and clinical factors and workload:
- Exposure time
- Tube supply (mA and kV)
- Number of films per day
- Distance from the tube to the organ to be examined.

LEVELS OF PROTECTION:
The Lead Equivalent declared Eq Pb 0.25 / 0.35 / 0.50 / 1.00mm (or their combinations front –back) is measured under the provisions of EN IEC 61331-1 : 2014, with a filtration equivalent to 2.5 mm Al. Clause 5.5.3 states that a relative standard uncertainty of 7 % should be taken into account in the decision of conformity in assigning the class of Lead equivalent thickness to the material under test.

TYPE: clothing and accessories for operator and patient.

USE LIMITS: NOT suitable for fire hazards, chemicals, cold and all those situations not mentioned in this note.

WARNINGS: the safety features mentioned are met only if the device is regularly worn, connected and in perfect condition.
We disclaim any responsibility for damages or consequences resulting from misuse.
Visually check the device before any use to make sure of its perfect condition, integrity and cleaning.
In case the device is damaged (split seams, cracks or holes, etc.), provide for its replacement. The device has to be worn by professional personnel: doctors, veterinaries, x-ray technicians, nurses and health workers. The patient device has to be worn under qualified personnel's supervision.

SIZING : according to EN IEC 61331-3:2014 frontal aprons, coats and skirts should reach knee length. If you don't find your size in the chart, we will make your apron custom sizing. The provisions of EN 13402-3 state the " Size designation of clothes "

STORAGE: store the clothing on a hanger or in its original packaging, in a cool and dry place, away from direct sun light and from heat sources. When the device gets unusable due to wear, lacerations or other reasons, it must be delivered to the designated collection point to be wasted.

CLEANING, DISINFECTION AND POSSIBLE STERILIZATION :
Use a moist cloth and mild soap for routine cleaning.
According to the "STANDARD PRECAUTIONS" of the Centre Disease Control in Atlanta, it is recommended to wear the protective device under the working coat during procedures at risks of splashes or aerosols of blood and / or biological fluids.
Stains of organic fluids on the device can be disinfected with a 1:100 solution of sodium hypochlorite.
The clothing may be sterilized with ethylene oxide or gas plasma of hydrogen peroxide.
Devices sensitive to humidity and high temperatures may be sterilized at low temperature, max. 40°C.
It is possible to soak the PPE in water for hand washing. Do not spin. Dry hanging in the open air.
The use of hydrogen peroxide allows a sterilization free of toxic waste and completely safe for humans and the environment.

LIFE TIME: check the device through X-Ray testing, we recommend an annual check from manufacturing date.

WARRANTY: two years from purchase date, for defects in material and manufacturing.

EC DECLARATION of CONFORMITY : available at the following internet link
https://www.nelsonxray.com/cert/DECLARATION-OF-CONFORMITY-NELSON-Oct-2019.pdf

CE MARK: The CE mark means the respect for the **Essential Health and Safety Requirements** of the PPE Regulation (EU) 2016/425, Annex II.

MARK IDENTIFICATION: the device has a label that contains the necessary data for its identification. The protection level values are indicated on the label of each device.

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Manufactured in ITALY by NELSONX SRL located in : via Sauro, 3 Cappella Maggiore TV ITALY www.nelsonxray.com