


TEXRAY.

Title: EU Declaration of Conformity, HeadPeace		Valid date: 2022-10-14	Author: FG 
Document ID: DC-DO-Declaration of Conformity HP	Revision: 7	Page: 1 of 2	Approved: PA

1. PPE (product, type, batch or serial number):

Texray™ HeadPeace, Model P-HP1025

2. Name and address of the manufacturer and, where applicable, his authorized representative:

Texray AB
Mail address: Stena Center
412 92 Göteborg, Sweden
Visiting address: Läraregatan 3
411 33 Göteborg, Sweden
E-mail: info@texray.io
Website: www.texray.io

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

Yes, Texray AB

4. Object of declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a color image of sufficient clarity may be included):

Texray HeadPeace x-ray protective equipment provides protection to the front and side of the head, with a nominal minimum lead equivalence of 0,25 mm narrow beam in the front and 0,25 mm narrow beam on the side, for x-ray tube voltage in the range of 70-110kV. The equipment is available in a range of three sizes.

The garment is described in the manufacturers Technical File entitled "TEXRAY™ HEADPEACE™ TECHNICAL FILE".

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation:

Regulation (EU)2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

6. Reference to the relevant harmonized standards used, including the date of the standard, or reference to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

IEC 61331-1:2014.

7. Where applicable, the notified body (SGS, 0598) performed in the EU type-examination (Module B) and issued the EU type-examination certificate 0598/PPE/21/2171 Issue 1. The notified body SGS United Kingdom Limited 0120 performed the UKCA type-examination (Module B) and issued the UKCA certificate 0120/PPE/221154 Issue 1.

8. Where applicable, the PPE is subject to the conformity assessment procedure: (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D):

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Certificate FI19/963147 (Module D) under surveillance of the notified body SGS Fimko Oy 0598.

9. Additional Information:

N/A

Signed on behalf of Texray AB,
Gothenburg, 2022-10-14



Petra Apell, CEO Texray AB