


TEXRAY.

Title: EU Declaration of Conformity, MindPeace		Valid date: 2022-10-14	Author: FG 
Document ID: DC-DO-Declaration of Conformity MP	Revision: 5	Page: 1 of 2	Approved: PA

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

MindPeace™, Models P-MP1035 (ThyroPeace); P-MP2035 (MindPeace mini); P-MP3035 (MindPeace).

2. Name and address of the manufacturer and, where applicable, his authorised 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 the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):

The thyroid collar family MindPeace, is a Personal Protective Equipment (PPE) designed to reduce external x-ray radiation exposure for the thyroid gland, neck and bottom cranial area of healthcare professionals performing or are present during radiological examinations or interventional surgical procedures. The x-ray (photon) attenuation and lead equivalence of MindPeace has been determined according to international standard IEC 61331-3:2014, with the modified broad beam geometry condition with an applied x-ray tube voltage range of 60-110 kV.

MindPeace is a product family of thyroid collars based on Texray protection material and are available in three different designs- ThyroPeace MP, MindPeace Mini and MindPeace. All three designs are available in three different sizes. ThyroPeace MP has a classic design to reduce radiation exposure of thyroid gland. MindPeace Mini has a front-faced protection flap to reduce the radiation exposure of the bottom cranial area whereas MindPeace has an extended protection flap to more efficiently reduce front- and side-faced radiation exposure of the bottom cranial area.

The product is described in the manufacturers Technical File entitled "MindPeace™ Technical File".

5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation 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. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

IEC 61331-1:2014, IEC 61331-3:2014.

7. Where applicable, the notified body SGS Fimko Oy 0598 performed the EU type-examination (Module B) and issued the EU type-examination certificate 0598/PPE/21/2172 Issue 2. The notified body SGS United Kingdom Limited 0120

TEXRAY.

Title: EU Declaration of Conformity, MindPeace		Valid date: 2022-10-14	Author: FG
Document ID: DC-DO-Declaration of Conformity MP	Revision: 5	Page: 2 of 2	Approved: PA

performed the UKCA type-examination (Module B) and issued the UKCA certificate 0120/PPE/221227 Issue 1.

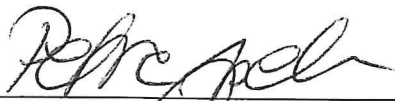
8. Where applicable, the PPE is subject to the conformity assessment procedure: (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) under surveillance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

Certificate F119/963147 (Module D) under surveillance of the notified body SGS Fimko Oy 0598.

9. Additional information:

N/A.

Signed on behalf of Texray AB,
Gothenburg, 2022-09-15



Petra Apell, CEO, Texray AB