

TEXRAY.

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| Title: DoC Coveragepage Name Change | | Valid date: 2020-08-26 | Author: FG |
| Document ID: DoC Coveragepage Texray | Revision: 1 | Page: 1 of 1 | Approved: PA |

Statement of name change: From Ten Medical Design AB to Texray AB

The company Ten Medical Design AB, also known as 10MD has changed its name to Texray AB. The legal entity, organisation and organisation number, remains the same (556890-3099).

The logotype of the company is from 2020-08-26:

TEXRAY.

These name changes are implemented on commercial basis and are not related to product performance or customer perception of the product appearance.

The products and their components are not affected by this change. Products produced henceforth will be labelled according to the new company brand profile.

The mailing address is the same as before:

Texray AB
Stena Center
412 92 Göteborg
Sweden

Visiting address has been changed to:

Texray AB c/o Stena Center
Läraregatan 3
411 33 Göteborg
Sweden

The following customer and user channels will hereafter be used:

www.texray.io
order@texray.io
info@texray.io

The previous channels; www.texray.io; order@10md.se; info@10md.se; are redirected to the corresponding addresses.

Texray AB declares that MindPeace™ and HeadPeace™ continues to conform with 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. The PPE is subject to the conformity assessment procedure conformity to type based on quality assurance of the production process (Module D)) under surveillance of the notified body SGS Fimko Oy 0598

Signed and authorized by:
Goteborg, 2020-08-26

Fredrik Gellerstedt
CEO
Texray AB

EU DECLARATION OF CONFORMITY No 3

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

NAFT™ HeadPeace, Model P-HP1025.

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

Ten Medical Design AB, 10MD
Stena Center 1A, Holtermansgatan 1
412 96 Göteborg, Sweden
Telephone: +46 705 735262
Website: www.10md.se

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

Yes, Ten Medical Design 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):

NAFT™ HeadPeace x-ray protective equipment provides protection to the front and side of head, with a nominal minimum lead equivalence of 0.25 mm narrow beam on 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 garments is described in the manufacturers Technical File entitled "Ten Medical Design AB" "NAFT™" BRAND, X-RAY PROTECTIVE GARMENTS, Rev 4.

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.

7. Where applicable, the notified body (name, number) SGS 0120 performed the EU type-examination (Module B) and issued the EU type-examination certificate GB19/963030 (reference to that certificate).

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

9. Additional information:

Signed for and on behalf of: ...
(place and date of issue):
(name, function) (signature):



GÖTTENBURG 2019-05-08

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Fredrik Gellerstedt CEO, Ten Medical Design AB