



In application of the Regulation (EU) 2016/425 of 9 March 2016 concerning the harmonization of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorized by the FPS Economy (Federal Public Services) has issued the following:

EU TYPE EXAMINATION CERTIFICATE

Nr. 031/2020/0340

This EU Type examination certificate is valid until 06 Mar 2025

to: **MDT Instruments Division bv, Hilvarenbeek**

for: **Vest and Kilt VK-X**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Regulation (EU) 2016/425.

For the argumentation, the following standards are used:

IEC 61331-3 Protective devices diagnostics medical X-radiation - Part3: Protective clothing, eyewear and protective patient shields

EN ISO 13688:2013 Protective clothing - General requirements

This is PPE of category III, subject to regular checks in accordance with article 19 of the European PPE Regulation. In agreement with the manufacturer's choice audits of the production process shall be carried out to assess the Conformity of type (Module D). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2021 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical documentation (As described in 2016/425 Annex III) that is registered with number 12400.

This certificate has been drawn up in accordance with the general certification regulation of Centexbel which is available via <https://www.centexbel.be>

Issued by Centexbel, Notified Body 0493, in Ghent, on 06 Mar 2020

Jan Laperre
Certification Manager

Attached: 1 Annex



ANNEX

EU TYPE EXAMINATION CERTIFICATE Nr. 031/2020/0340

1. Applicant

MDT Instruments Division bv
Bukkumweg 26
5081 CT Hilvarenbeek
Netherlands

2. Description

The PPE described in this certificate are designed to protect its user against X-rays as used in medical diagnosis applications. The manufacturer refers to the international standard IEC 61331-3, which is used to demonstrate the protection offered.

Degree of protection:
IEC 61331-3:2014
mm Pb 0.25 - 0.35 - 0.50
60kV – 110kV

3. Materials and accessories

Protective layer : PU, several colors possible
Hardware and accessoires possible: nylon, velcro, elastic material, click closure, shoulder pads, webbing, bias tape, sewing thread

Description/Picture of article

Article **Vest and Kilt VK-X**



The above picture is a general picture of the article. Possible variations of the above article can be present in the technical file.

Note :

Any modification in material, design, or other technical features must be brought to the attention of the Notified Body.