

Occupational Safety Research Institute, v.v.i.

Jeruzalémská 1283/9, 110 52 Praha 1, Czech Republic
Notified Body 1024



EU TYPE-EXAMINATION CERTIFICATE No. 1024/E-057/2022

This EU type-examination certificate is issued to:

Authorised representative: ONIKO–Europe, s.r.o., Pod Višňovkou 1662/21,
140 00 Praha 4 – Krč, Czech Republic

Identification number: 24285081

Manufacturer: ONIKO Private Enterprise, ID 19242964
55/57, Voloska street, 04070 Kiev, Ukraine

PPE product: **Shield Collar – model ON-RA 219**

It is certified that the manufacturer's technical file and above mentioned PPE product have been assessed and found to be in accordance with the essential health and safety requirements of Regulation (EU) 2016/425 of the European parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC, as recorded in Report No.1024/ZZ-027/2022 which is an integral part of this Certificate.

When examined the model was found to meet all of the relevant requirements of the appropriate harmonized standard(s)/specification(s):

ČSN EN 61331-3 ed.2:2015 **Protective devices against diagnostic medical X.radiation – Part 3:
Protective clothing, eyewear and protective shields
(idt. EN 61331-3:2014)**

ČSN EN ISO 13688:2014 **Protective clothing – General requirements
(idt. EN ISO 13688:2013)**

The certification was performed according to the certification scheme of Regulation (EU) 2016/425 Module B. Marking and instructions have been assessed in the Czech language

Certificate is valid until 4. 4. 2027

For and on behalf of Occupational Safety Research Institute
Notified Body No. 1024:

Date of Issue: 4. 4. 2022



Ing. Jiří Tílhon, Ph.D., LL.M.

Description and picture of the PPE product:



The collar is designated for protection of patient against X-ray ionization in professional application according to instruction for using.

The product is classified in category III and shall only be used in conjunction with conformity assessment procedure Module C2 within the meaning of Regulation (EU) 2016/425.



Graphical appearance of CE mark. In the event of the involvement of a notified body in the stage of manufacturing check (category III, Module C2 or D) its distinguishing number shall be added to CE mark.