



EU Declaration of Conformity

in accordance with
PPE Regulation (EU) 2016/425

Authorized representative:
ONIKO-Europe s.r.o.
Pod Visnovkou 1662/21
14000 Praha 4
Czech Republic
Organization ID number: 24285081

Producer:
ONIKO PE
Voloska 55/57
04070 Kyiv
Ukraine
Organization ID number: 19242964

This declaration is issued under the sole responsibility of the manufacturer.

It declares that the manufacturer's technical file and PPE products described in appendix
**List of products - Personal Protection Equipment against X-ray
produced by company ONIKO,**

complies with the requirements of **Regulation (EU) 2016/425** of the European Parliament
and of the Council of 9 March 2016.

The object of declaration is in conformity with the relevant Union harmonization legislation:

**CSN EN 61331-3:2015 Protective devices against diagnostic medical X-radiation –
Part 3: Protective clothing, eyewear and protective patient shields**

CSN EN ISO 13688:2014 Protective clothing – General requirements

The PPE of III risk category is subject to the type based conformity assessment procedure on
internal production control plus supervised product checks at random intervals (Module C2)
under surveillance of the notified body:

Occupational Safety Research Institute
(Výzkumný ústav bezpečnosti práce, v.v.i.)
Jeruzalémská 1283/9
116 52 Praha 1 - Nové Město
Czech Republic

Notified Body 1024


Anatolii Kolesnikov
director ONIKO PE

Kyiv,
April 15, 2022

Appendix 1

List of products - Personal Protection Equipment against X-ray produced by company ONIKO

ONIKO-Europe s.r.o.
Pod Visnovkou 1662/21
140 00 Praha 4
Czech Republic

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www.oniko.cz

Organization ID number: 24285081
Tax identification number: CZ24285081
Conducted by the Municipal Court in Prague under the brand C 193075

List of products - Personal Protection Equipment against X-ray produced by company ONIKO

No	No. of CE certificate	Certificate is valid until	Marking of model	Model name in English	Model name in Czech
1	No. 1024/E-122/2020	31.12.2025	ON-RP101	Shield collar small	Límeč ochranný malý
2	No. 1024/E-128/2020	31.12.2025	ON-RP103	Dental apron standard	Zástěra stomatologická standardní
			ON-RP102	Children dental apron	Zástěra stomatologická dětská
3	No. 1024/E-129/2020	31.12.2025	ON-RP106	Shield pelerine	Pelerína ochranná
			ON-RP105	Shield pelerine for children	Pelerína pro děti
			ON-RP107	Pelerine for panoramic shots	Pelerína pro panoramatické snímkování
4	No. 1024/E-131/2020	31.12.2025	ON-RP114	Shield plates kit №1, 6 pcs.	Fólie ochranné – sada č. 1, 6 ks.
			ON-RP115	Shield plates kit №2, 4 pcs.	Fólie ochranné – sada č. 2, 4 ks.
5	No. 1024/E-130/2020	31.12.2025	ON-RP110	Front apron for gonad shielding: for children standard Male gonad shield Female ovarian shield Hip Shield for Children	Zástěra ochranná pro gonády dětská standardní
			ON-RP111		Ochrana gonád pro muže
			ON-RP112		Ochrana vaječníků
			ON-RP113		Ochrana gonád při vyšetření kyčlí kojenců
			ON-RP108		
6	No. 1024/E-123/2020	31.12.2025	ON-RP104	One-side apron for children	Zástěra jednostranná dětská
			ON-RA202	One-side apron standard	Zástěra jednostranná standardní
			ON-RA203	One-side surgical apron, with shoulder straps	Zástěra jednostranná chirurgická s rukávy
			ON-RA204	One-side surgical apron, with belt	Zástěra jednostranná chirurgická s páskem
			ON-RA205	One-side surgical apron, with velcro fastener	Zástěra jednostranná chirurgická se suchým zipem
			ON-RA214	One-side apron with shoulder straps	Zástěra jednostranná s ramenními popruhy
7	No. 1024/E-126/2020	31.12.2025	ON-RA206	Protective skirt standard	Sukně ochranná standardní
			ON-RP116	Protective skirt for children	Sukně ochranná pro děti
8	No. 1024/E-127/2020	31.12.2025	ON-RA207	Protective waistcoat	Vesta ochranná
			ON-RA208	Waistcoat with increased front overhang	Vesta ochranná se zvětšeným přesahem vepředu
9	No. 1024/E-124/2020	31.12.2025	ON-RA209	Two-side apron	Zástěra dvoustranná
10	No. 1024/E-125/2020	31.12.2025	ON-RA210	Sleeveless coat	Kabát bez rukávů
			ON-RA211	Short-sleeved coat	Kabát s krátkými rukávy
			ON-RA212	Coat with removable sleeves	Kabát se snímacími rukávy
11	No. 1024/E-132/2020	31.12.2025	ON-RA213	Protective shoe covers	Kryt bot
12	No. 1024/E-057/2022	04.04.2027	ON-RA219	Shield collar	Límeč ochranný
13	No. 1024/E-058/2022	04.04.2027	ON-RA220	Shield collar large	Límeč ochranný velký
14	No. 1024/E-060/2022	04.04.2027	ON-RP117	Gonad Protection kit with Belt	Sada krytů gonád s páskem
15	No. 1024/E-056/2022	04.04.2027	ON-RA218	One-side apron with shoulder straps Comfort	Zástěra jednostranná s ramenními popruhy Comfort
16	No. 1024/E-059/2022	04.04.2027	ON-RA221	Sleeveless coat	Kabát bez rukávů
17	No. 1024/E-055/2022	04.04.2027	ON-RA217	Protective gloves with open inner hand	Ochranné rukavice



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