

EU declaration of conformity

1. Company name and address:

Company name	Filterpak Oy Ab Ltd
Address	Hangonkyläntie 67
Postal code and city	10900 HANKO, Finland
SRN	FI-MF-000007331
Website	www.filterpak.fi

2. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

3. The UDI-DI as referred to in Part C of Annex VI:

06430078970006	(Blue-Edition)
06430078970013	(Black-Edition)
06430078970020	(White-Edition)
06430078970044	(Pink-Edition)

4. Product identification:

Nesu® Professional surgical mask Type II
Basic UDI-DI: 643007897NeSuTypeIIPE (Blue-, Black-, White- or Pink-Edition)

5. Risk class of the device in accordance with the rules set out in Annex VIII:

Class 1
Duration of use: Short term

6. The device that is covered by the present declaration is in conformity with following relevant Union legislation:

- (EU) 2017/745
- 93/42/EEC

7. References to any CS used and in relation to which conformity is declared:

- SFS-EN 14683:2019 + AC:2019
- SFS-EN ISO 13485:2016
- SFS-EN ISO 14971:2019
- SFS-EN ISO 10993-5 and 10993-10

8. Additional information: www.filterpak.fi and www.nesu.fi

9. Guarantee of conformity:

Place and time Hanko, 26.7.2021

Filterpak Oy Ab Ltd



Peter Nordlund, CEO