

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
Website www.filterpak.fi

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

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

Provided after 05/2021

4. Product identification:

Nesu® Professional UltraSoft surgical mask Type II (90 g)
Product model: UL90-TII

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:

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

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

Accredited test institute used for conformity assessment:

HygCen Austria GmbH, ID 0196
Report: B 24977 III / 25.08.2020 + B 24977a III / 30.7.2020

8. Additional information:

www.filterpak.fi an www.nesu.fi

9. Guarantee of conformity:

Place and time Hanko, 11.12.2020.

Filterpak Oy Ab Ltd



Peter Nordlund, CEO