

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

06429830045519 Nesu® Professional UltraSoft

4. Product identification:

Nesu® Professional UltraSoft surgical mask Type II (90 g)
Basic UDI-DI: 643007897NeSuTypeIIPE, 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:

- (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

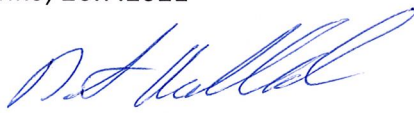
8. Additional information:

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