

## 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	<a href="http://www.filterpak.fi">www.filterpak.fi</a>

**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:**

06430078970037	(White-Edition)
06430078970051	(Blue-Edition)
06430078970068	(Black-Edition)
06430078970075	(Pink-Edition)

**4. Product identification:**

Nesu<sup>®</sup> Professional surgical mask Type IIR  
Basic UDI-DI: 643007897NeSuTypeIIR3W (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](http://www.filterpak.fi) and [www.nesu.fi](http://www.nesu.fi)

**9. Guarantee of conformity:**

Place and time Hanko, 26.7.2021

Filterpak Oy Ab Ltd



Peter Nordlund, CEO