

# EC Declaration of Conformity

## For Medical Face Masks Type II, IIR

Essity Hygiene and Health AB  
SE-405 03 Göteborg  
Sweden

hereby declares the sole responsibility that Medical Face Mask that reduces the risk of spreading infective agents, according to the enclosed article list, fulfill the requirements according to EU Medical Device Regulation 2017/745 and standard EN 14683 Medical face masks.

The products are classified as medical devices class I according to Medical Device Regulation 2017/745 and the GMDN code is 35177 Surgical face masks and the CND code is T020601 Standard Surgical Face Mask. The test requirements as stated in EN 14683 has been passed for the respective type.

### Test results

Tests 1-4 have been tested by RISE Research Institutes of Sweden, an accredited external test institute, and the tests are made according to EN 14683 as below.

Test	Test method	Type II	Type IIR	Result
1	Bacterial filtration efficiency (BFE), (%)	≥98	≥98	Passed
2	Differential pressure (Pa/cm <sup>2</sup> )	<40	<60	Passed
3	Splash resistance pressure (kPa)	Not required	≥16.0	Passed
4	Microbial cleanliness (cfu/g)	≤ 30	≤ 30	Passed

These Medical Face Masks are sold under different brand and names through different channels.

Mölnadal, on October 15<sup>th</sup> 2020



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Romana Stefek  
Global Regulatory Affairs/Product Safety Director  
LM Essity Hygiene and Health AB

**Essity Hygiene and Health AB**  
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Document Name	Document ID	Version	Page
Declaration of Conformity	FORM-0733	3.0	1(2)

## Article list

Article number	Name
3965300	ZEWA Medical Face Mask 30/3 MD
3965400	ZEWA Medical Face Mask 9/10 MD
48809600	LOTUS Medical Face Mask 9/10 MD
83628000	TEMPO Medical Face Mask 30/3 MD
83628100	TEMPO Medical Face Mask 9/10 MD
12600100	Tork Medical Type IIR Face Mask,10x50p
12600200	Tork Protective Type II Face Mask,10/5x10p

This Declaration of Conformity for Essity Medical Face Masks is valid until a new DoC is issued,

Seat: Göteborgs kommun. Registration number: SE556007-2356

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