

EC Declaration of Conformity

For Medical Face Masks Type II, IIR

Essity Hygiene and Health AB
 SE-405 03 Göteborg
 Sweden
 SRN number: SE-MF-000000004

hereby declares being the manufacturer* of 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 devices are intended for to be worn by patients, care givers and other persons to reduce the risk of spread of infections, and 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 14683:2019 + AC:2019 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 14683:2019 + AC:2019 as below.

Test	Test method	Type II	Type IIR	Result
1	Bacterial filtration efficiency (BFE), (%)	≥98	≥98	Passed
2	Differential pressure (Pa/cm ²)	<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.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Möndal, on January 13th. 2021



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

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 Möndals Bro 2, Möndal

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Article list

Article number	Name	Basic UDI-DI	UDI-DI/Device identifier
3965300	ZEWA Medical Face Mask 30/3 MD	73225405004482	7322541329345
3965301	ZEWA Medical Face Mask 30/3 MD	73225405004482	7322541329345
3965400	ZEWA Medical Face Mask 9/10 MD	73225405004482	7322541329383
3965401	ZEWA Medical Face Mask 9/10 MD	73225405004482	7322541329383
48896800	LOTUS Medical Face Mask 9/10 MD SE/NO	73225405004482	7322541347141
48896801	LOTUS Medical Face Mask 9/10 MD SE/NO	73225405004482	7322541347141
48809600	LOTUS Medical Face Mask 9/10 MD FI/DK	73225405004482	7322541329093
48809601	LOTUS Medical Face Mask 9/10 MD FI/DK	73225405004482	7322541329093
48809602	LOTUS Medical Face Mask 9/10 MD FI/DK	73225405004482	7322541329093
48809500	LOTUS Medical Face Mask 30/3 MD FI/DK	73225405004482	7322541329055
48809501	LOTUS Medical Face Mask 30/3 MD FI/DK	73225405004482	7322541329055
48809400	LOTUS Medical Face Mask 9/10 MD FR	73225405004482	7322541329017
48809401	LOTUS Medical Face Mask 9/10 MD FR	73225405004482	7322541329017
48809300	LOTUS Medical Face Mask 30/3 MD FR	73225405004482	7322541328973
48809301	LOTUS Medical Face Mask 30/3 MD FR	73225405004482	7322541328973
83628000	TEMPO Medical Face Mask 30/3 MD	73225405004482	7322541329130
83628001	TEMPO Medical Face Mask 30/3 MD	73225405004482	7322541329130
83628100	TEMPO Medical Face Mask 9/10 MD	73225405004482	7322541329178
83628101	TEMPO Medical Face Mask 9/10 MD	73225405004482	7322541329178
12600101	TORK Medical Type IIR Face Mask, 10x50p	7322540400157G	7322541329734
12600100	TORK Medical Type IIR Face Mask, 10x50p	7322540400157G	7322541329734
12600201	TORK Protective Type II Face Mask, 10/5x10p	7322540400157G	7322541329772
12600200	TORK Protective Type II Face Mask, 10/5x10p	7322540400157G	7322541329772

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

**per definition in Medical Device Regulation (EU) 2017/745*

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Seat: Göteborgs kommun. Registration number: SE556007-2356

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