

EU TYPE-EXAMINATION CERTIFICATE

Regulation (EU) 2016/425, MODULE B

0598/PPE/23/3263 Issue 1

Product Respiratory protective device. Filtering half mask to protect against particles

Model JedX Medcare FFP2 NR

Trademark -

Certificate Holder / Manufacturer SJT-Investment Group Ltd
Köysikuja 1, 01640 Vantaa, Finland

Product complies with the applicable essential health and safety requirements of Regulation (EU) 2016/425 and standard(s) mentioned below

Standard(s) EN 149:2001 + A1:2009

Other Information FFP2 NR

This certificate shall be used in conjunction with conformity assessment procedure module C2 or D.

Validity This certificate is valid until 2028-07-04.

Date of issue 2023-07-04

SGS Fimko Ltd

Signature



Minna Torenus
Senior Specialist

SGS Fimko Ltd is a Notified Body (0598) according to the Personal Protective Equipment Regulation (EU)



Additional information This certificate replaces certificate 0598/PPE/200885, Issue 1, issued 2021-01-05.

The full details of the assessment are given in Certification report no. 0598/PPE/23/3263/R.

Technical Evaluation Report No. 0598/PPE/23/3263/R

1. Certificate holder / Manufacturer

SJT-Investment Group Ltd
 Köysikuja 1, 01640 Vantaa
 Finland

2. Description and identification of the product

Model: JedX Medcare FFP2 NR

Product type: Respiratory protective devices. Filtering half mask to protect against particles, FFP2 NR

Applied standard:
 EN 149:2001+A1:2009

Performance level(s):
 FFP2 NR

Size range: -

Description: White or black folded, 5-layered, filtering half mask with ear-straps

Pictures of the products



JedX Medcare FFP2 NR, white



JedX Medcare FFP2 NR, black

3. Applied legislation

X	Regulation (EU) 2016/425 (CE marking)
	Regulation (EU) 2016/425 as brought into GB law and amended (UKCA marking)

4. Evaluation

The documentation supplied by the manufacturer is listed in Appendix 1.

Materials and the product have been tested in accordance with the requirements of the applied standard and by accredited testing laboratories. The models of the product supplied by the applicant conform to the technical documentation.

The product and the technical documentation relating to it comply with the requirements of the applied legislation.

Note: Any modification in design, materials, or in the technical documentation, must be brought to the attention of SGS Fimko.

Appendix 1 Technical documentation
Appendix 2 Document history

End of Technical Evaluation Report.

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Notified Body 0598

SGS Fimko Ltd

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Business ID 0978538-5

Member of the SGS Group (SGS SA)

Technical documentation regarding Technical Evaluation Report No. 0598/PPE/23/3263/R

Model: JedX Medicare FFP2 NR
 Certificate holder / Manufacturer: SJT-Investment Group Ltd, Köysikuja 1, 01640 Vantaa, Finland

Item of technical documentation	Document identification	Assessment
1. Signed application	2023-05-10 Jari Nurminen	Adequate
2. Product drawing, construction, and material list	Materiaalilista 2023-05-08, versio 3. JedX Medicare FFP2 tekninen aineisto 1.1, 2020-12-30 Selvitys materiaalien väleistä, 2021-04-08.	Product is identified and described. Materials are specified.
3. Compliance with the applied legislation and its applicable essential health and safety requirements	The compliance assessment is based on reports mentioned below items 3.1-3.5	
3.1. SGS Fimko assessment of essential health and safety requirements	2023-06-28	The applied harmonized standard EN 149:2001+A1:2009 supports the relevant requirements.
3.2. Test report	INSPEC International Limited, Test Report No: 1.20.12.29, 2020-12-15	JedX Medicare FFP2 NR fulfils the requirements of EN 149:2001+A1:2009 for level FFP2 NR.
3.3. Draft information sheet	JedX Medicare. Instructions on packaging materials: 1351B_JedX_Medicare_FFP2_NR_1kpl_FI_SE_Black_lowres and 1351B_JedX_Medicare_FFP2_NR_1kpl_FI_SE_White_lowres. Received 2022-05-09.	Document meets the requirements of the applied legislation and standard.
3.4. Product markings	Product samples received 2023-03-23. Drafts of packaging material 1351B_JedX_Medicare_FFP2_NR_1kpl_FI_SE_Black_lowres and 1351B_JedX_Medicare_FFP2_NR_1kpl_FI_SE_White_lowres received 2022-05-09.	Markings meet the requirements of the applied legislation and standard.
3.5. Risk assessment	Risk Assessment for Particle filtering half mask: Riskianalyysi Medicare FFP2, 2020-07-29	Adequate
4. Description of the production quality system and related product control and test facilities	Agreement with SGS Fimko 0598 for the EU quality control assurance system, module D (PPE category III products)	Adequate for module B.

Document history of Technical Evaluation Report 0598/PPE/23/3263/R

2023-06-28	<p>Technical Evaluation Report No. 0598/PPE/23/3263/R issued for EU type-examination certificate No. 0598/PPE/23/3263, Issue 1</p> <p>Material list was specified in this new issue of the certificate.</p> <p>Prepared by: Erja Mäkelä</p>
2021-01-05	<p>The product has a previous EU type-examination certificate 0598/PPE/200885, Issue 1. Its latest EU type examination report 0598/PPE/200885/R has been prepared on 2021-04-27.</p>

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