EU TYPE-EXAMINATION CERTIFICATE
Regulation (EU) 2016/425, MODULE B
0598/PPE/23/3269 Issue 1

Product	Respiratory protective device. Filtering half mask to protect against particles
Model	JedX Medcare FFP3 NR D
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	- This certificate shall be used in conjunction with conformity assessment procedure module C2 or D.
Validity	This certificate is valid until 2028-07-03.
Date of issue	2023-07-03
	SGS Fimko Ltd
Signature	

Erja Tammela
Senior Specialist

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

SGS Fimko Ltd
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Additional information This certificate replaces certificate 0598/PPE/210005, Issue 2, issued 2021-08-03.

The full details of the assessment are given in Certification report no. 0598/PPE/23/3269/R.

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

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Technical Evaluation Report No. 0598/PPE/23/3269/R

1. Certificate holder / Manufacturer

SJT-Investment Group Ltd
Köysikuja 1, 01640 Vantaa
Finland

2. Description and identification of the product

Model: JedX Medcare FFP3 NR D

Product type: Respiratory protective devices. Filtering half mask to protect against particles, FFP3 NR D

Applied standard:
EN 149:2001+A1:2009

Performance level(s):
FFP3 NR D

Size range: -

Description: White folded, 6-layered, filtering half mask with ear-straps

Picture of the product

JedX Medcare FFP3 NR D, white

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 model of the product supplied by the applicant conforms 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.

Notified Body 0598

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Technical documentation regarding Technical Evaluation Report No. 0598/PPE/23/3269/R

Model: JedX Medcare FFP3 NR D

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 Medcare FFP3 tekninen aineisto, 2020-07-29	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 3.1-3.6	
3.1. SGS Fimko assessment of essential health and safety requirements	2023-06-29	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 Medcare FFP3 NR D fulfils the requirements of EN 149:2001+A1:2009 for level FFP3 NR.
3.3. Test report	INSPEC International Limited, Test Report No: 1.21.06.46, 2021-06-18	JedX Medcare FFP3 NR D fulfils the EN 149:2001+A1:2009 requirements against clogging, D.
3.4. Draft information sheet	JedX Medcare. Instructions on packaging materials: 1739W_JedX_Medcare_FFP3_NR_1kpl_FI_SE_White _lowres Received 2022-05-09.	Document meets the requirements of the applied legislation and standard.
3.5. Product markings	Product samples received 2023-03-23. Drafts of packaging material 1739W_JedX_Medcare_FFP3_NR_1kpl_FI_SE_White _lowres Received 2022-05-09.	Markings meet the requirements of the applied legislation and standard.
3.6. Risk assessment	Risk Assessment for Particle filtering half mask: Riskianalyysi Medcare FFP3, 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/23/3269/R

2023-06-29	Technical Evaluation Report No. 0598/PPE/23/3269/R issued for EU type-examination certificate No. 0598/PPE/xx/xxxx, Issue 1 Material list was specified in this new issue of the certificate. Prepared by: Erja Mäkelä
2021-03-08	The product has a previous EU type-examination certificate 0598/PPE/210005, Issue 2. Its latest EU type-examination report 0598/PPE/210005/R has been prepared on 2021-03-08.