EU TYPE-EXAMINATION CERTIFICATE
0598/PPE/210005

Product	Filtering half mask to protect against particles, FFP3 NR
Model/Type	JedX Medcare FFP3 NR
Trade mark	JedX Medcare
Certificate Holder / Manufacturer	SJT-Investment Group Ltd, Köysikuja 1, 01640 Vantaa, Finland
	This product complies with the applicable essential health and safety requirements of Regulation (EU) 2016/425 and standard(s) mentioned below
Standard	EN 149:2001+A1:2009
Additional information	-
	This certificate shall be used in conjunction with conformity assessment procedure module C2 or D
Validity	This certificate is valid until 4 January 2026. Certificate Issue 1. Certified since 5 January 2021.
Date of issue	5 January 2021
	SGS Fimko Ltd
Signature	

Mikko Hirvonen
Research Scientist

Anna Ruhala
Product Line Manager

The full details of the assessment are given in Certification report No. 0598/PPE/210005/R.
SGS Fimko Ltd is a Notified Body (0598) according to the Personal Protective Equipment Regulation (EU) 2016/425.

Notified Body 0598
SGS Fimko Ltd
Takomotie 8, FI-00380 Helsinki, Finland
t. +358 9 696 361 www.sgs.fi
Business ID 0978538-5 Member of the SGS Group (SGS SA)

Additional information -

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

Notified Body 0598

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EU type-examination report

This EU type-examination report is for EU type-examination certificate No. 0598/PPE/210005, Issue 1.

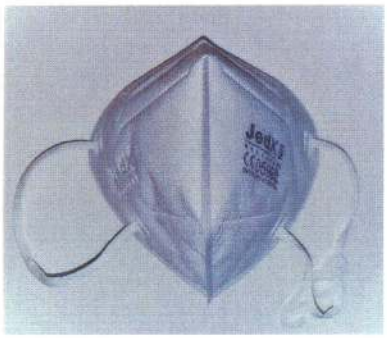
1. Applicant

SJT-Investment Group Ltd
Köysikuja 1
01640 Vantaa
Finland

2. Description and identification of the product

Product name:	JedX Medcare FFP3 NR
Type:	Filtering half mask to protect against particles, FFP3 NR
Description:	White layered half mask
Manufacturer:	SJT-Investment Group Ltd, Köysikuja 1, 01640 Vantaa, Finland

Picture of the product:



JedX Medcare FFP3 NR

3. Adequacy and validity of the technical documentation

The documentation supplied by the applicant is listed in Appendix 1. Technical documentation is considered adequate and valid. The product has been tested in accordance with a harmonized European standard EN 149:2001+A1:2009 by accredited testing laboratories. The model of the product supplied by the applicant conforms to the technical documentation.

4. Compliance with essential health and safety requirements

The product and the technical documentation relating to it comply with the relevant essential health and safety requirements stated in the Regulation (EU) 2016/425 Annex II.

Note: Any modification in design, materials, or in the technical documentation carried out on this type-examined product must be brought to the attention of SGS Fimko.

Appendix 1	Technical documentation
Appendix 2	Document history

End of EU type-examination report.

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

Notified Body 0598

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Technical documentation regarding EU type-examination report 0598/PPE/210005/R

Product name: JedX Medcare FFP3 NR

Applicant: SJT-Investment Group Ltd, Köysikuja 1, 01640 Vantaa, Finland

Item of technical documentation	*Document identification*	*Assessment*
1. Application for the EU type examination	2021-01-05 Jari Nurminen	Adequate
2. Product drawing, construction, and material list	Materiaaliluettelo (02), 30.07.2020, JedX Medcare tekninen aineisto, 29.07.2020	Product is identified and described. Materials are specified.
3. Compliance with Regulation (EU) 2016/425 essential health and safety requirements	The compliance assessment is based on the reports mentioned below items 3.1-3.5	
3.1. SGS Fimko assessment of essential health and safety requirements	2021-01-04	The applied harmonized standard EN 149:2001+A1:2009 supports the relevant requirements.
3.2. INSPEC International Limited	Test Report No: 1.20.12.29, 2020-12-15	JedX Medcare fulfils the requirements of EN 149:2001+A1:2009 for level FFP3.
3.3. Instructions for use	JedX Medcare. Instructions on packaging. Packaging received 2020-12-22.	Document meets the requirements of the PPE Regulation and EN 149:2001+A1:2009.
3.4. Product markings	Product markings on sample and its packaging. Sample received 2020-12-22.	Markings meet the requirements of the PPE Regulation and EN 149:2001+A1:2009.
3.5. Risk assessment	Risk Assessment for Particle filtering half mask: Riskianalyysi Medcare FFP3, 29.07.2020	Adequate
4. Description of the production quality system and related product control and test facilities	The assessment is based on the documents mentioned below, items 4.1 and 4.2	
4.1. Quality control by notified body	Agreement with SGS Fimko on the EU quality control system for the final product, module D for PPE category III products.	The agreement document is adequate. The first control shall be conducted within a year from the date of the certificate 0598/PPE/210005.
4.2. Quality control at the manufacture	Referenced to ISO 9001:2015 Certificate, Identity Number FIHSK11102944A, Expiry date: 30 June 2023; Tuotantoprosessi-yleiskuva, 11.06.2020 Laadunvalvontamenetelmät 2020-09	Adequate

Document history of EU type-examination certificate 0598/PPE/210005 and report 0598/PPE/210005/R

2021-01-05	EU type-examination certificate 0598/PPE/210005, Issue 1