

Client assessment report on conformity of personal protective equipment on Regulation (EU) 2016/425 module D

Type of personal protective equipment	Respiratory protective devices
Names of the products and EU type examination certificates and issue dates	Listed in appendix 1
Basis of certification	Regulation (EU) 2016/425 EN 149:2001+A1:2009
Certificate holder	SJT-Investment Group Ltd Köysikuja 1 01640 Vantaa
Manufacturing sites	Same as above
Audit visit no	5
Date(s) of audit(s)	2026-03-03
Place of audit	Köysikuja 1, 01640 Vantaa
Lead auditor	Seija Ryyänen
Additional members	Hanna Koskinen, trainee
Present	Jari Nurminen Lailannie Nurminen Viktoria Bhatia Juha Mikkonen Arto Manninen consultant

The objectives of this audit were to determine conformity of the management system or parts of it with audit criteria and its:

- ability to ensure applicable statutory, regulatory and contractual requirements are met
- effectiveness to ensure the client can reasonably expect to achieve specified objectives, and
- ability to identify as applicable areas for potential improvements

Audit Objectives: To confirm that the PPE conformity control process, has been established and implemented in accordance with the requirements of the module D according to PPE Regulation (EU) 2016/425.

Executive Summary

The assessment day was an integrated audit on ISO 9001:2015, ISO 14001:2015, Regulation (EU) 2016/425 module D.

SJT-Investment Group Ltd is a respirator manufacturer, including two CAT III products of PPE which are under SGS Fimko Module D, JedX Medicare FFP3 NR and JedX Medicare FFP2 NR.

Head office with production, product development, quality control and warehouse are located in Vantaa, Finland. Company has one manufacturing site.

The audit team conducted a process-based audit focusing on significant aspects/risks/objectives required by the PPE Regulation (EU) 2016/425.

A sampling process was used, based on the information available at the time of the audit. The used audit methods were interviews, observation of activities and review of documentation and records.

The following items were audited on-site:

- Changes in operations
- Management review (risk management, customer complaints, continual improvements, quality targets, resources, infrastructure)
- Customer satisfaction
- Internal audits
- Competences, maintaining and orientation of new person for PPE certification process
- Supplier selection, evaluation process
- Quality control process (quality requirement, traceability, control of nonconforming products, corrective and preventive actions)
- Testing, calibrations
- The list of CAT III PPE products, which are under module D of SGS Fimko, were confirmed
- Control of documents (control of changes, prevention of unintended changes, storage time)
 - Reviewed module B certificate
 - 0598/PPE/23/3263 (JedX Medicare FFP2 NR)
 - Design, markings, labels, instruction of use and declaration of conformity -documents were checked to corresponds to relevant module B certificate 0598/PPE/23/3263 (JedX Medicare FFP2 NR)
 - Checked product was JedX Medicare FFP2 NR
- Visit at production and warehouse

Observations and Improvement Opportunities

Observations

- The company's quality and environmental systems are well-established and documentation in accordance with the requirements exists.
- Management reviews have been conducted systematically and comprehensively annually.
- The management is active, committed and develops the organization's operations.
- Internal audits are performed annually in all operations and corrective actions have been taken to improve the management system.
- There have been no complaints in respirator production in 2025.
- Purchasing practices appear to be smooth and the supply chain for production raw materials has been reliable. Upon receipt, the manufacturer's test reports are documented and the organization performs its own testing on a sample basis. There has been no need for complaints for a long time.
- Suppliers are systematically assessed annually and corrective measures are implemented if necessary.
- The production process and quality control of respiratory protective devices are well-established and meet the requirements of the Personal Protective Equipment Regulation.
- The production premises are clean, bright and suitable for respiratory production.
- The recyclability of respiratory materials is being investigated, but no sensible use has been found so far.
- Parallel European suppliers for the materials are in focus. If new materials are added to the certificate, the products shall be tested in an accredited laboratory and the notified body shall be contacted for an EU type-examination certificate review.

Improvement Opportunities

- Attention should be paid to the management of documented information. For example, the storage, availability and version control of the documents used in the EU type inspection process.
- Shortening of European Union is EU both in English and Finnish (although EU is not needed to mention in DoC).

Conclusion

Based on the documents and discussions, the quality system of SJT-Investment Group Ltd corresponds to the requirements of module D and the essential safety and health requirements of Regulation (EU) 2016/425

Place and date: Helsinki, Finland 2026-03-10


 Sanna Karkkula
 Senior Specialist

Next D assessment Spring 2026

End of Assessment report

Names of the products, EU type examination certificates

Table 1. Products type examined according to Regulation (EU) 2016/425.

EU type examination certificate	Issue Date	Expiry date	Notified body	Product name
0598/PPE/23/3263	04-07-2023	04-07-2028	0598 SGS	JedX Medcare FFP2 NR
0598/PPE/23/3269	03-07-2023	03-07-2028	0598 SGS	JedX Medcare FFP3 NR D

Table 2. Manufacturing sites

Name of manufacturing site	Address	Country
SJT-Investment Group Ltd	Köysikuja 1, 01640 Vantaa	Finland