

DECLARATION OF CONFORMITY

Manufacturer: SJT-Investment Group Oy
Köysikuja 1
01640 Vantaa
Finland

Product: **JEDX respirator mask IIR**

(models JedX Medicare FFP2 NR 1351 W UDI-DI: 06429810381002, JedX 3971 W FT HL UDI-DI: 06429810381507, JedX 3972 FT HL UDI-DI: 06429810381545)

Disposable respirator mask. Intended for protecting against harmful droplets and splashes.

This declaration of conformity has been issued under the sole responsibility of the manufacturer.

The product declared is in conformity with the relevant Union harmonization legislation related to medical devices, including MDR regulation (EU) 2017/745.

Harmonized product standards applied: EN 14683:2019+AC:2019

Other applied standards: EN ISO 15223-1:2021 (labeling symbols)
EN ISO 14971:2019 (risk analysis)
EN ISO 10993-1:2009 (biological evaluation)
EN ISO 10993-23:2021 (tests for irritation)
EN ISO 13485:2016 (quality management system)

Product risk class according to (EU) 2017/745 Annex VIII rule I: Class I

Conformity assessment route: manufacturer conformity declaration combined with technical documentation according to (EU) 2017/745 Annex II and Annex III.

The product is subject to the manufacturer's continuous internal quality control and manufacturing quality surveillance. The manufacturer holds the product technical file as evidence of compliance.

Signed on behalf of SJT-Investment Group Oy:

Vantaa, Finland 13.10.2023


Jari Nurminen
Managing Director

