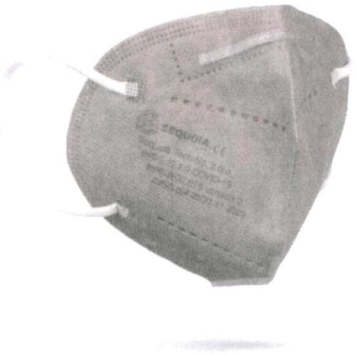
SEQUOIA TECH

EU DECLARATION OF CONFORMITY

The declaration of conformity is issued under the sole responsibility of the manufacturer

Manufacturer:

Sequoia Tech Sp. z o.o.
Ul. Przemysłowa 10
98-235 Błaszki
Poland



Object of the declaration:

Sequoia ViralShield Med SVSG.20 1.0

CE marked products, to which this declaration relates, are classified as:

- per rule 1 of Annex IX of the Medical Device Directive 93/42/EEC, as Class I devices,
- PPE: filtering half mask to protect against COVID-19, as the object of the declaration is in conformity with the relevant Union harmonization legislation PPE-R (EU) 2016/425.

Manufactured in conformity with the Quality Management System based on the PN-EN ISO 13485 standard.

Notified body FORCE Certification A/S (0200) performed the EU type-examination (Module B) and issued the EU type-examination certificate No. 0200-PPE-09732 version 1.

References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

- essential requirements of the Directive 93/42/EEC,
- PPE-R RfU 02/075 version 2,
- EN 14683:2019+AC: 2019 – Medical face masks – Requirements and test methods,
- EN ISO 14971: 2012 – Medical devices – Application of risk management to medical devices,
- EN ISO 15223-1: 2016 – Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
- EN 1041:2008 – Information supplied by the manufacturer of medical device,
- EN ISO 10993-1:2009 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Signed for and on behalf of:

Błaszki, Poland 08.12.2020	Jerzy Pietrucha Chief Executive Officer
Place and date of issue	Name and function

Signature