screentec

CE

EU DECLARATION OF CONFORMITY

Screentec Medical Face Mask (type II, non-sterile), **Scr MFM02_CE, 009051797**

1. Manufacturer: Screentec Oy, Konekuja 2, 90620 Oulu, Finland.

2. EU declaration of conformity is issued under the sole responsibility of the manufacturer, Screentec Oy.

3. Screentec Medical Face Mask (type II, non-sterile), Scr MFM02_CE, 009051797 is intended for single use by healthcare professionals to protect both patients and healthcare professionals. The purpose of the medical face mask is to protect the user from airborne particles and the patient from particles entrained by the user's breath. The product is neither a respirator nor personal protective equipment.

Screentec Medical Face Mask (type II, non-sterile), Scr MFM02_CE, 009051797 is also intended for single use by patients and other lay users to reduce the risk of spread of infections.

Product picture:

4. The face mask is categorized to class I medical device.

5. The face mask that is covered by the present declaration is in conformity with Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC and, it fullfills requirements of European standard EN 14683:2019 + AC:2019. The face mask is tested according the standard in the accredited laboratory. The results of tests are presented in report:

SCRE-369245-220720 TECNAL Suu-nenäsuojatestitulokset Class II PASSED.pdf.

6. On behalf of Screentec Oy, Managing Director

12.1.2022 Oulu

Antti Tauriainen

Date and place

Managing Director, Screentec Oy

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