

DECLARATION OF CONFORMITY



In accordance with Directive 93/42/EEC (ANNEX VII) and subsequent amendments and supplements concerning medical devices.

SANINTEK S.R.L.
Via B. Ferracina, 32
36043 Camisano Vicentino (VI)
Italy

DECLARE THAT

The product surgical mask type II

MODELL	COMFORT
CLASS	I non-sterile and without measuring function
YEAR OF PRODUCTION	2020

It was built in accordance with the following directives and technical standards:

- Dir. 93/42/EEC, D.L. 24/02/97 n.46, D.L. 25/02/98 N.95 Council Directive concerning medical devices
- Implementation of Directive 93/42/EEC concerning medical devices. Amendments to Legislative Decree 24/02/97 n.46
- UNI EN 14683:2019, UNI EN ISO 10993-1:2010, UNI EN 14971:2012, UNI EN 1041:2009, UNI EN ISO 15223-1:2012

It therefore complies with the applicable directives and regulations.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Camisano Vicentino (VI), Italy

Date

Legal representative
A handwritten signature in black ink, appearing to be 'A. Miller', written over the text 'Legal representative'.