DECLARATION OF CONFORMITY

CE

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 IIR

MODELL	PRIMA IIR
CLASS	I non-sterile and without measuring function
YEAR OF PRODUCTION	2021

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.

In addition, the device, as established by the Ministerial Decree of 21 December 2009, 'Modifications and integrations to the decree of 20 February 2007 containing the New modalities for the fulfilments foreseen by article 13 of the legislative decree of 24 February 1997, no. 46 and subsequent modifications and for the registration of active implantable devices as well as for the registration in the Repertoire of medical devices', was registered in the list of the Ministry of Health with the registration identification code **BD/RDM 2068934.**

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

Camisano Vicentino (VI), Italy

Date

Legal representative