

EC DECLARATION OF CONFORMITY



In accordance with Council Directive 93/42/EEC of 14 June 1993 (ANNEX VII) concerning medical devices and subsequent amendments and additions.

Sitisa SA
Via Pobbia, 12
6514 Sementina
Switzerland

declares that

the medical face mask (type IIR)

MODEL	325.00317
CLASS	I non sterile e without a measuring function
DATE OF MANUFACTURE	2020

Is conformal to the following directives and standards:

- Dir. 93/42/EEC
- EN 14683:2019, EN ISO 10993-1:2010, EN 14971:2012, EN 1041:2009, EN ISO 15223-1:2012

Therefore, the product complies with the essential health and safety requirements of the current legislation.

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

Sementina (Switzerland)

Date 15.07.2020

Signature of the legal representative

A handwritten signature in black ink, appearing to read 'P. Collins', is written over a horizontal line. The signature is stylized and cursive.