

EC Approval of conformity

In line with the Annex VII of the directive 93/42/EEC on Medical Devices

Us,

OUVRY SAS

24 avenue Joannès Masset - ZA Gorge de loup 69009 Lyon France

guarantee and declare, under our sole responsibility, that the device :

OCOV® ref. 100011AA

And his filters OCOV® ref. 111014AA et ref.111015AA

Medical device class I according to regulation 1 of the annex IX of the European Directive 93/42/EEC

complies with the applicable requirements of Directive 93/42/EEC and the French Public Health Code.

The mask OCOV® fulfil the requirements of the NF EN 14683+AC August 2019 as Medical face masks, type II intended for use by healthcare professionals in operating theaters or other medical facilities with similar requirements.

This declaration is based on the following elements:

- Documents from Technical File NT-20-1201 demonstrating compliance with the essential requirements of Directive 93/42/EEC.
- Certificate no. 569051 of approval of the quality management system in accordance with the requirements of the ISO 9001: 2015 standard, issued by the accredited body no. 4-0552.

This for the period of validity of the certificate, i.e. until: 19 June 2025.

Lyon, 19 June 2020

Ludovic OUVRY, Président

