



Str. Atomistilor n. 12, Magurele
077125, provincial di Ilfov, Romania



DECLARATION OF CONFORMITY

Subscribed INOX SA , headquartered in Magurele , No. 12 , Atomistilor Street, Ilfov County , registered ONRC J 23 / 2005 / 2006 , with tax identification code RO 409430 , represented by Mr. Calin Sandel as General Manager, we declare on our own responsibility, as manufacturer that the product:

Disposable surgical mask 3 layers / 3 folds with elastic - medical device class 1, type II

Characteristic	Imposed value / characteristic type IIR	Value / characteristic obtained
BFE bacterial filtration efficiency	$\geq 98 \%$	99.86% - 99.98%
Breathability	$< 60 \text{ Pa / cm}^2$	41.18 / Pa / cm ²
Sprinkler resistant (kPa)	$> 16 \text{ (PASS / FAIL)}$	PASS
Sterility	$< 30 \text{ (cfu / g)}$	corresponds

- Complies with the requirements of **SR-EN 14683 + AC 2019** ;
- Complies with the essential requirements applicable in Annex 1 of Directive 93/42 / EEC on medical devices (transposed by HGR54 / 2009 on the conditions of placing medical devices on the market, as subsequently amended and supplemented) ;
- Complies with the evaluation procedures in accordance with Annex VII of Directive 93/42 / EEC;
- It is included in the risk class and in the classification rule, according to Annex IX of Directive 93/42 / EEC.

Magurele, Ilfov 14.07.2020

General Manager,
Calin Sandel


