



12 Atomistilor Street, Magurele
077125, Ilfov county, Romania

EU DECLARATION OF CONFORMITY

1. Product type: **Disposable Surgical Mask 3 Layers/3 folds and elastic , Type II**
2. Name and address of manufacturer: INOX S.A. Registered headquarters: 12 Atomistilor Street, Magurele, Ilfov, poste code 077125.
3. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration: **Disposable Surgical Mask 3 Layers/3 folds and elastic , Type II**
5. The object of the Declaration described at point 4 is in conformity with the relevant Union harmonization legislation of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.
6. References to the relevant harmonized standards used and to other technical specifications in relation to which conformity of products is declared:
 - International standard EN ISO 9001 – 2015 – Quality Management System;
 - International standard SR EN 14683+AC :2019 – Medical face masks. Requirements and test methods;
 - International standard SR EN 13485:2016 – Medical devices — Quality management systems — Requirements for regulatory purposes ;
 - Directive: 93 /42/EEC – related to medical devices;
 - GD 54 /2009 – related to conditions to place the medical devices on the market
7. Three- Ply Elastic / Three- Layer Disposable Surgical Mask is a medical device, class 1, type II R, highly resistant, of blue/ green color, designed to protect against: bacterial penetration, splash with body fluids, risk of spread of infections, as per SR EN 14683+AC:2019 and Directive 93/42/EEC. The filtering is made on the entire area. It comes with elastic loops for securing the ears and metal strip covered in plastic for nose bridge. It allows for breathing without restrictions. Odorless, fiberglass-free and latex free.

Features of mask: approximate sizes of mask: 175x95 mm, approximate weight 3 grams.

Structure of Three- Ply Elastic / Three- Layer Disposable Surgical Mask: the 2 outer and inner layers are made of non-woven fabric of spunbonded polypropylene (PP) type, the middle layer (particle filter) is non-woven fabric of melt-blown polypropylene (PP) type, of white color, bacterial filtration efficiency ≥ 98 % (SR EN 14683+AC:2019); metal strip of galvanized wire covered in polyethylene (PE), elastic (nylon).

Place and date of issuance of declaration:

INOX SA, No. 12 Atomistilor Street, Magurele, Ilfov

14.July.2020

General Manager
Calin Sandel

