



## **EC DECLARATION OF CONFORMITY**

MANUFACTURER : Sanipack Solutions Amb. Ve Saglik Ürünleri San. Tic. A.S.

ADDRESS : Ivedikkoy Mah.1495. Cad. No:3/1, Yenimahalle

Ankara, Turkey

TELEPHONE : +90 312 911 2007

EMAIL : info@sanipack.com

Classification : Medical Device Directive - ANNEX IX, Rule 1, Class I

Conformity Assessment : MDD 93/42 / EEC Medical Device Directive

Annex VII-EC Declaration of Conformity

**GENERIC NAMES OF PRODUCTS:** 

- SURGICAL FACE MASK

GMDN Code : 35177

GMDN Name : Mask, Surgical, Single Use

We herewith declare that above mentioned product meet the provisions of the Council Directive 93 / 42/ EEC for Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied : EN ISO 13485:2016 , MDD 93/42/EEC,

Brand Name : SANIMASK (Registered Trademark)

Valid Until : 04.08.2021

Place / Date : ISTANBUL / 04.08.2020

Signature : FATMA ŞEN

**DIRECTOR**