

**CLASSIFICATION : CLASS- OTHER (NON-STERILE AND NON-MEASURING FUNCTION)**

**RULE 1**

**CONFORMITY 93/42/EEC EK – VII**

**ASSESSMENT ANNEX:**

**GMDN CODE : 35177 – Mask, Surgical, disposable**

**VMSK 01 – DISPOSABLE 2-PLY FACE MASK (SINGLE)**

**VMSK 02 – DISPOSABLE 2-PLY FACE MASK (50 PCS/PACKAGE)**

**VMSK 03 – DISPOSABLE 3-PLY FACE MASK (SINGLE)**

**VMSK 03 – DISPOSABLE 3-PLY FACE MASK (50 PCS/PACKAGE)**

**VCMSK 01 – DISPOSABLE 2-PLY FACE MASK (SINGLE)**

**VCMSK 02 – DISPOSABLE 2-PLY FACE MASK (50 PCS/PACKAGE)**

**VCMSK 03 – DISPOSABLE 3-PLY FACE MASK (SINGLE)**

**VCMSK 04 – DISPOSABLE 3-PLY FACE MASK ((50 PCS/PACKAGE)**

**PRODUCT NAME :**

**VMSK 01 – DISPOSABLE 2-PLY FACE MASK (SINGLE)**

**VMSK 02 – DISPOSABLE 2-PLY FACE MASK (50 PCS/PACKAGE)**

**VMSK 03 – DISPOSABLE 3-PLY FACE MASK (SINGLE)**

**VMSK 03 – DISPOSABLE 3-PLY FACE MASK (50 PCS/PACKAGE)**

**VEMSK 01 – DISPOSABLE 2-PLY FACE MASK (SINGLE)**

**VEMSK 02 – DISPOSABLE 2-PLY FACE MASK (50 PCS/PACKAGE)**

**VEMSK 03 – DISPOSABLE 3-PLY FACE MASK (SINGLE)**

**VEMSK 04 – DISPOSABLE 3-PLY FACE MASK ((50 PCS/PACKAGE)**

THE PRODUCTS MENTIONED ABOVE COMPLY WITH THE REQUIREMENTS FOR MEDICAL DEVICES DECREE 93/42/EC (2007/42/EV), AS DEFINED IN DIRECTIVE 2001/83/EC ARTICLE 1, WHICH PROMOTES THE FUNCTION OF THE MEDICAL DEVICE ON THE HUMAN BODY AND WHICH ALONE, IS CONSIDERED A HUMAN DRUG, ARE INCLUDED IN DIRECTIVE 93/42/EC OF THE EUROPEAN PARLIAMENT. WE DECLARE THAT THE HUMAN BLOOD DERIATIVE, AS DESCRIBED IN SECTION 7.4 AND IN THE REVISED 2007/47/EC DIRECTIVE, DOES NOT CONTAIN PHTHALATE AS AN INTEGRAL PART OF THE ANIMAL-ORIGIN TISSUES MENTIONED IN DIRECTIVE 2003/32/EC, AS DEFINED IN THE FORM AMENDED IN DIRECTIVE 67/548/EHS. ALL SUPPORTING DOCUMENTS ARE IN THE MANUFACTURERS PREMISES.

## RELATED STANDARDS

TS EN ISO 13485:2016	TS EN ISO 14971:2013
93/42/EEC	EN ISO 10993-2018