



# TEMRA®

I N T E R N A T I O N A L

## TEMRA MASK DUAL PSM 03

### PROTECTIVE SURGICAL MODEL

### FFP2 NR / IIR – EASY BREATHING



EN 149:2001+A1:2009  
EN 14683:2019+AC:2019

ISO: 22609  
EN ISO 11737-1

REGULATION (EU) 2016/425 FOR PPE  
MEDICAL DEVICE REGULATION (EU) 2017/745

EN ISO: 10993-1  
EN ISO: 10993-5  
EN ISO: 10993-10

CE 2834

BASIS UDI-DI: PP11451PSM0323

# TEMRA MASK DUAL - PSM 03

## PROTECTIVE SURGICAL MODEL

### FFP2 NR/IIR – EASY BREATHING



- **MEDICAL USAGE - FOR SURGICAL INTERVENTIONS**
- **MODEL: PSM03**
  - Version: PSM03 – T (Ties)
  - Version: PSM03 – L (Loops)
  - Version: PSM03-J-T (Junior, Ties)
  - Version: PSM03-J-L (Junior, Loops)
- **Class: FFP2 NR / TYPE IIR**
- **Size: 20,5cm x 8,5cm (Adult)**
- **Size: 17,5CM x 6,5cm (Junior)**
- **Highest dual protection against infections for healthcare professionals and patients (Bacterial filtration efficiency > 99%)**
- **Effectively blocks droplets in the air (Particle filtration efficiency > 98%)**
- **Unique viral filtration efficiency > 99%**
- **Easy breathing due to innovative breathing and filter technology**
- **Germ-free and bio-compatible, highest hygienic standard**
- **Splash resistance against blood and body fluids**
- **Material: Non-woven fabric, melt blown polypropylene, hot air cotton**
- **Conforms to Standard EN149:2001+A1:2009 according to Regulation (EU) 2016/425 for Personal Protective Equipment**
- **Conforms to Standard EN 14683:2019 + A1:2019 according to Medical Device Directive 93/42 EEC and Medical Device Regulation (EU) 2017/745**
- **Box content: 20 Individually packed units**

PSM03 T



PSM03 L



# ACCREDITATIONS & REGISTRATIONS

## TEMRA MASK DUAL - PSM03



### CCQS Certification Services Limited

European Union Notified Body N° 2834, Dublin, Ireland  
Regulation (EU ) 2016/425) for Personal Protective Equipment  
Reference Standard: EN 149:2009 + A1:2009

Module B EU Type Examination Certificate N° :

CE – PC – 201203-738-02-9A

Module C2 Production Monitoring Certificate N°:

CE – PC – 201203-738-FPC- A

### HYGCEN Austria GmbH

Certification Body (EN ISO 17025), Bischofshofen, Austria  
Medical Device Regulation (EU) 2017/745  
Reference Standards:

EN 14683:2019 + AC:2019 (+ISO 22609 & 11373)

Certificate N°: 2126410/020

EN ISO 10993-1 (-5/-10)

Certificate N°: 2126410/021



### EUDAMED

European databank for medical devices

TEMRA MASK DUAL PSM03

BASIS UDI-DI: PP11451PSM0323

TEMRA INTERNATIONAL LTD

SRN: MT-MF-000001253



### BfArM (Germany)

Federal Institute for Drugs and Medical Devices

TEMRA MASK DUAL PSM03

N° DE/CA61/00322317

TEMRA INTERNATIONAL GmbH

N° DE/0000049472



### IFA (Germany)

Information Service for Pharmaceutical Market

TEMRA INTERNATIONAL LTD

CIN: 11451



## GALLERY PSM03 - VERSIONS

### PSM03 – T (HEAD TIES)



### PSM03 – L (EAR LOOPS)



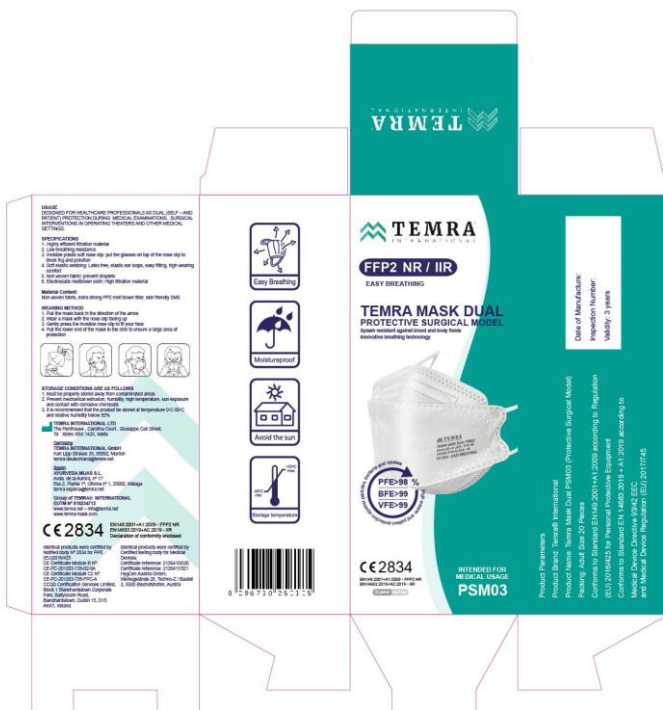
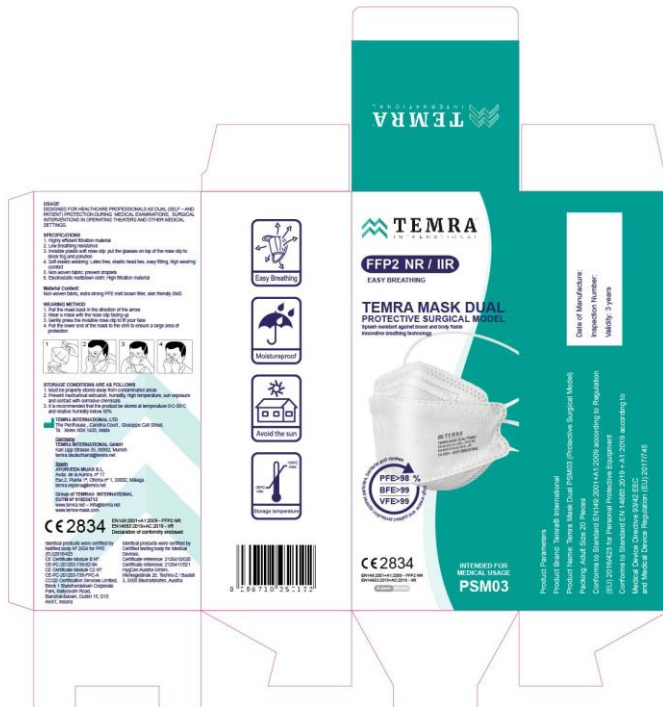
### PSM03 – J – T (JUNIOR - HEAD TIES)



### PSM03 – J – L (JUNIOR – EAR LOOPS)



## PACKAGING PSM03 – (TIES) & (LOOPS)





# PACKAGING PSM03 JUNIOR – (TIES) & (LOOPS)



## PACKAGING-PARAMETERS

1 Carton contains 50 innerboxes

1 innerbox PSM03 contains 20 masks

Each mask is packed individually

Weight per carton: 10 KG

Units per carton PSM03: 1000 masks



## PACKAGING

### TEMRA MASK DUAL PSM03

- 1 innerbox PSM03 contains 20 masks. (Image 1)
- One English and local language user information / instruction sheet per box with Declaration of conformity attached and enclosed (Image2)
- Every unit is packed in an individual plastic bag
- Every individual packing unit carries an extra nose foam to reduce condense for wearers of glasses (Image 3)
- Tie adjusters or loop clips will be fixed on or attached to the mask (Image 4 & 5)

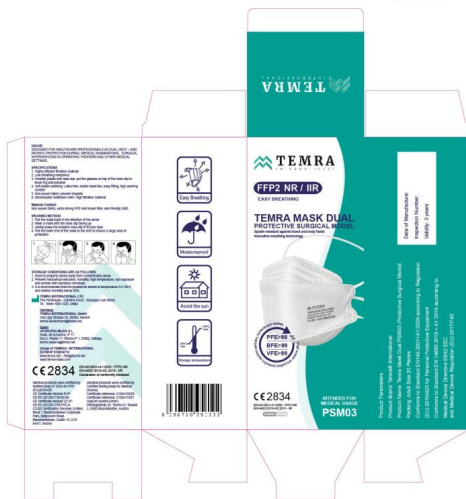


Image 1



Image 2



Image 3



Image 4



Image 5



## TEMRA MASK DUAL - FFP2 NR / IIR - PROTECTIVE SURGICAL RESPIRATOR EASY BREATHING · Product Information and User Guide:

Language:	English
Brand:	Temra® International
Name:	TEMRA MASK DUAL
Model:	PSM01 (Protective Surgical Model)
Basis UDI-DI:	PP11451PSM0323
Version - L:	PSM03 – L (Ear Loops)
Version - T:	PSM03 – T (Head Ties)
Version –J-L:	PSM03 –J-L (Junior Ear Loops)
Version –J-T:	PSM03 – J-T (Junior Head Ties)
Classification:	FFP2 NR / TYPE IIR
Specials:	Innovative technology for easy breathing Dual protection for healthcare professionals and patients
Description:	Filtering half mask, folding design, 205x85 mm (adult size), 170x65mm (junior size), latex free elastic ear loops or head ties and adjustable nose clip of minimum 9cm lengths
Standard/Regulation:	EN149:2001+A1:2009 / (EU) 2016/425 – PPE
Standard/Regulation:	EN 14683:2019 + AC:2019 / MDR (EU) 2017/725



### Product Information:

<b>Manufacturer:</b>	<b>TEMRA INTERNATIONAL LTD</b> The Penthouse, Carolina Court, Giuseppe Cali Street, Ta'Xbiex MT - XBX 1425 EUDAMED - SRN: MT-MF-000001253 <hr/> <b>Germany:</b> <b>TEMRA INTERNATIONAL GmbH</b> Karl Lipp Strasse 35, DE - 80992, Munich <a href="mailto:temra.deutschland@temra.net">temra.deutschland@temra.net</a> <b>Spain:</b> <b>AYURVEDA MIJAS S.L.</b> Avda. de la Aurora, nº 17 Esc.2, Planta 1ª, Oficina nº 1, ES - 29002, Málaga <a href="mailto:temra.espana@temra.net">temra.espana@temra.net</a> <b>Group of TEMRA® INTERNATIONAL</b> EUTM Nº 018224712 <a href="http://www.temra.net">www.temra.net</a> – <a href="mailto:info@temra.net">info@temra.net</a> <a href="http://www.temra-mask.com">www.temra-mask.com</a>
<b>Management System:</b>	ISO: 9001:2015 ISO: 13485:2016

<b>Composition:</b>	Non woven fabric, extra strong PFE melt blown filter, breathable cotton padding fabric, skin friendly SMS, latex free elastic ear loops or head ties and adjustable nose clip.
<b>Sterile or non sterile:</b>	Non sterile (but undergoing post production Ethylene Oxide sterilization process)
<b>Properties:</b>	Protective surgical respirator, particle, virus and bacteria filtering half mask as respiratory protective device with optimized, medical graded breathability due to the application of innovative technology, splash resistant against blood and body fluids, bio compatible, highest wearer comfort, high dual protection against aerosols and infectious agents.
<b>Packaging:</b>	20 pieces per box.
<b>Lot №:</b>	Specification on the box.
<b>Expiration Date:</b>	36 months after production date.
<b>Storage and Handling Conditions</b>	Product should be stored in a clean, dry and ventilated area with a humidity of less than 50%.
<b>Warning:</b>	The filtration performance can deteriorate with long-term use. At reuse exists the danger of a cross contamination.
<b>Performance according to Standard: EN 149: 2001 + A1: 2009:</b>	Particle filtration efficiency (PFE): > 98% General protection level (GPL): > 95% Breathing resistance: Inhalation 30 l/min < 0.3, 95 l/min < 1.17, Exhalation 160 l/min < 2.17.
<b>Performance according to standard: EN 14683 + 2019 + AC: 2019</b>	Bacteria filtration efficiency (BFE): > 99% Breathability – Differential pressure: < 60 Pa/cm.
<b>ISO 22609: EN ISO 11737:</b>	Splash resistant Bioburden: < 30 cfu/g.
<b>EN ISO 10993 - 1 EN ISO 10993 - 5 EN ISO 10993 – 10</b>	Bio compatible Non toxic Non skin irritating.
<b>Medical Usage:</b>	DESIGNED FOR HEALTHCARE PROFESSIONALS AS DUAL (SELF – AND PATIENT) PROTECTION TO PREVENT THE TRANSMISSION OF INFECTIOUS AGENTS DURING MEDICAL EXAMINATIONS, SURGICAL PROCEDURES IN OPERATING THEATERS AND OTHER MEDICAL SETTINGS.

## WARNINGS:

- Do not touch the outside of the mask. If so, wash your hands well.
- This mask is for single use only. Do not reuse.
- The mask must be replaced in good time. Long-term use is not recommended.
- It is recommended that you stop using the mouthpiece if you experience discomfort or side effects during use.
- The product is not washable. Please ensure that it is used within a valid time period.

Store in a dry, ventilated place away from open flames and combustible materials.

Change the mask if it is wet, short of breath, dirty or after 8 hours of use.

## USER GUIDE:

### How to place the foam for extra comfort

Peel off the protective layer of the foam and stick it, following the nose clip lines, centered at the interior of the mask.

### How to put on a face mask (Version L)

1. Wash your hands with soap and water or hand sanitizer before touching the mask.
2. Remove a mask from its packaging, making sure that the mask does not have any obvious cracks, holes, or damage.
3. The side of the mask with a flexible and rigid edge faces up.
4. Elastic ear loop mask: Hold the mask by the loops. Pull the loops behind your ears.
5. Pull the lower part of the mask down so that it covers your mouth and chin.
6. Shape the mask's nose clip to match the shape of the nose for the best possible seal.





## USER GUIDE:

### How to put on a face mask (Version – T)

1. Hold the respirator in place with one hand and spread the edges to fully open it with the other hand. Bend the nose clip on top of the respirator to form a slight curve.
2. Turn the respirator over to expose the two headbands, then spread them apart with your thumb and forefinger. Hold the headbands with your index finger and thumb and the respirator under your chin.  
Place the top of the headband on the crown of your head, over your ears, not under them.  
Place the lower strap on the back of your head under your ears.
4. Make sure the respirator is flat against your cheeks.
5. Form the nosepiece over the bridge of your nose, then press well with your fingers until you have a good face fit. If you can't get a good fit, don't go ahead.

Follow these five steps to fit your respirator correctly

*Tip: It may be helpful to look in the mirror when fitting your respirator*



### How to remove a mask

1. Wash your hands with soap and water or hand sanitizer before touching the mask.  
Do not touch the front mask. The face of the mask is contaminated. Only touch the clips / tapes. Follow the instructions below for the type of mask you are using.
2. Ear strap mask: Hold both ear straps and carefully lift and remove the mask.  
Dispose of the mask in a waste container according to your waste procedures. Wash your hands with soap and water or hand sanitizer.
3. Tie-on mask: Hold both ties and carefully lift and remove the mask.  
Dispose of the mask in a waste container according to your waste procedures. Wash your hands with soap and water or hand sanitizer.



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