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INTERNATIONAL

ALL ABOUT
TEMRA MASK DUAL
(ULTRA) PROTECTIVE SURGICAL MODELS
FFP2-3 NR / IIR – EASY BREATHING

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

ISO:	**22609**
EN ISO:	**11373-1**
EN ISO:	**10993-5**
EN ISO:	**10993-10**
ISO:	**9001:2005**
ISO:	**13485:2016**

USER GUIDELINES – COMPARISON STUDY - PRODUCT INFORMATION
Update: 09/01/2020

USER GUIDELINES & COMPARISON STUDIES

PROTECTIVE SURGICAL RESPIRATORS

The following shall serve as guideline for the usage of face masks in medical and surgical environments for healthcare professionals.

It relates the principal existing mask categories and classifications in comparison to a new upcoming innovative type of combined respirator capable to comply with all requirements which are imperative for medical professionals with a view to enjoy optimized protection, wearing and breathing comfort.

Temra® International, as manufacturer of medical protective equipment underlines the advantages of its new creation of protective surgical respirators, mainly but not limited, for health care institutions and their professionals.

FFP2

PARTICLE FILTERING HALF MASKS

FFP2 MASK SAMPLE

Definition:

Particle-filtering half-masks are adapted to the wearer's face, mostly of white color, which pertain to the category of Personal Protective Equipment (PPE-Category III) according to Regulation (EU) 2016/425, evaluated under Standard: EN 149:2001+A1: 2009.

Classification into FFP grades (Filtering Face Peace) is carried out according to filtration efficiency and permeability (inward leakage), as well as breathability:

FFP1 refers to particle filtration efficiency equal to or higher than 80% and maximum permeability equal to or less than 22%, which equates to a general protection level of at least 78% and maximum breathing resistance for inhalation of 0,6 mbar (30l/min), 2,1 (95l/min) and for exhalation 3,0 mbar (160l/min).

FFP2 refers to particle filtration efficiency equal to or higher than 94% and maximum permeability equal to or less than 8%, which equates to a general protection level of at least 92% and a maximum breathing resistance for inhalation of 0,7 mbar (30l/min), 2,4 (95l/min) and for exhalation 3,0 mbar (160l/min).

FFP3 refers to particle filtration efficiency equal to or higher than 99% and a maximum permeability equal to or less than 2%, which equates to a general protection level of at least 98% and a maximum breathing resistance for inhalation of 1,0 mbar (30l/min), 3,0 (95l/min) and for exhalation 3,0 mbar (160l/min).

Filtration test method: Paraffin oil and sodium chloride with 95l / min
Breathability test method: Mbar 30l/min, 95l/min and 160l/min

Further testing requirements: Skin compatibility, flammability, carbon dioxide content of inhalation air, head harness and field of vision

In accordance with its protection level, filtering face peace masks protect the wearer and others from aerosols transmissions of infectious agents.

II-IIR

Medical-Surgical Masks

Definition:

(Medical Device Directive 93/42/EEC and Medical Device Regulation (EU) 2017/745):

EN 14683: 2019 + AC: 2019 Standard specifies the composition, design, operating requirements (Annex A – User information) and test methods of surgical masks intended to limit the transmission of infectious agents from medical personnel to patients during surgical procedures, during examinations or other medical settings with similar requirements.

Commonly known medical, surgical three layer face masks offer general protection to patients and others, but do not offer sufficient self – protection for the wearer from infectious aerosols due to its high leakage, as these masks are usually not adapted to the wearers face.

Surgical masks are classified in accordance to their filtration efficiency and breathability:

Type I means a bacterial filtration efficiency (BFE) of ≥ 95% and differential pressure of < 40 Pa/cm2

Type II means a bacterial filtration efficiency (BFE) of ≥ 98% and differential pressure of < 40 Pa/cm2

Type IIR (used by surgeon during operations in sterile operation rooms) means a bacterial filtration efficiency (BFE) of ≥ 98%, splash resistance and differential pressure of < 60 Pa/cm2

Filtration test method (Annex B): Staphylococcus Aureus ATCC 6538 with 28,3l/min

Breathability test method (Annex C): Pa/cm2 under air flow with 8l/min

Splash resistance test method (ISO 22609) : 21,3 kPa of synthetic blood pressure

Further testing requirements:

Microbiological cleanliness (Annex D or ISO 11373-1): > 30 CFU/g

Biocompatibility (ISO 10993-5/10)

FFP2-3 NR / IIR

PROTECTIVE SURGICAL RESPIRATOR

Definition:

A Protective Surgical Respirator Class FFP2 Type IIR or FFP3 Type IIR complies with both Standards EN 149:2001 according to Regulation (EU) 2016/425 for Personal Protective Equipment and EN 14683:2019 according to Medical Device Directive 93/42/EEC and Medical Device Regulation (EU) 2017/745.

As particle-filtering surgical half-masks adapted to the wearer's face with a maximum protection against the exposure to body fluids and blood, as well as dual protection for clinical professionals and patients against mutual transmissions of infectious agents via aerosols; to be used by surgeons and health care professionals during surgical procedures in operating theaters and medical examinations and treatments of patients especially with open wounds.

In order to be qualified as a Dual Standard Protective Surgical Respirator FFP2 IIR, the following standards must be met:

Principal requirements and methods:

Particle filtration efficiency: FFP2 $\geq$ 94% & FFP3 $\geq$ 99% / Natrium Chloride and Paraffin Oil, 95l/min

Inward leakage < 8% or General protection level: FFP2 $\geq$ 92% & FFP3 $\geq$98% / (Leakage / Filtration)

Bacterial filtration efficiency $\geq$ 98% (Staphylococcus Aureus ATCC 6538, 28,3l/min)

Splash resistance against blood and body fluids (21,3 kPa of synthetic blood pressure)

Breathing resistance for inhalation air: FFP2 > 0,7 mbar & FFP3 > 1,0 mbar (30l/min) / FFP2 > 2,4 & FFP3 > 3,0 (95l/min) and for exhalation > 3,0 mbar (160l/min).

Microbial cleanliness or Bio Burden > 30 CFU/g

Biocompatibility

Other requirements :

Skin compatibility, flammability, carbon dioxide content of Inhalation air, head harness and field of vision

Despite being medical graded, a Protective Surgical Respirator does not need to be tested under Annex C of Norm 14683:2019, which means, there is no need of passing the medical breathability differential pressure test, whose measurement methods and parameters are different from the breathing resistance test for protective masks of personal protective equipment and whose requirements in comparison are more restrictive.

FFP2-3 NR / IIR - EASY BREATHING (ULTRA) PROTECTIVE SURGICAL RESPIRATORS

TEMRA MASK DUAL PSM02
FFP2 / IIR EASY BREATHIING

https://cdnmedia.eurofins.com/european-west/media/12146819/medical_face_mask_report_v13.pdf

3.2 Breathability: A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material. Test should be performed in accordance with the requirement of Annex C of EN 14683:2019 [1]. The differential pressure of the medical face mask shall conform to the value given for the relevant type.

If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in EN European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).

(Ultra) Protective Surgical Respirators have been officially exempted from the medical breathability testing requirement in order to obtain its qualification as surgical grade type IIR, subject to compliance with the remaining test requirements of the medical normative Standard EN 14683:2019 + AC:2019.

The reason for this exemption is obvious. FFP2 and FFP3 graded protective respirators are classified as personal protective equipment and usually composed by 4 or 5 layers of non woven fabric, hot air cotton and melt blown polypropylene, granting the highest possible levels of particle filtration and protection, while adapted to the face minimizing inward leakage of air. This composition, even though it is highly protective, is significantly decreasing the wearers breathing comfort, especially for surgeons during surgical procedures and healthcare professionals at intensive care units performing their activities in multiple occasions under major stress and highest mental concentration level requirements. Breathing difficulties and shortage of oxygen could drastically impact on their performance efficiency.

At the same time, common medical face masks usually allow professionals to breath comfortably, but without providing an adequate self- protection and without eliminating the risk of exposure of their patients to transmission of infectious agents and diseases.

The formula of success is therefore to create an Easy Breathing Protective Surgical Respirator which is capable to provide the highest level of protection, while achieving at the same time a medical breathing grade and being therefore in full compliance without exemptions under medical and personal protective equipment dual standard requirements, at levels of FFP2/IIR and FFP3/IIR.

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In General, particle-filtering protective surgical masks require the following markings in accordance with EU regulations, including the specification of the norm, classification according to filtration efficiency and usability.

According to this, a rule-compliant marking of a protective surgical mask approved in Europe and certified by a Notified Body, such as in case of the Temra Mask Dual PSM03 – Easy Breathing -, is composed by :

EN 149: 2001 (corresponds to the EU norm and relevant testing standard for personal protective equipment)

EN 14683:2019 (corresponds to the EU norm and relevant testing standard for medical devices)

FFP2 (Corresponds to the classification according to particle filtration efficiency - "Filtering Face piece" minimum degree of 94% and GPL of 92%, respectively)

IIR (Corresponds to the classification according to bacterial filtration efficiency – “BFE” minimum degree of 98% and indicates its qualification as splash resistant)

NR (Corresponds to usability - "Not Reusable")

CE 2834 (Seal of approval CE with identification number of the notified body)

USAGE RECOMMENDATION FOR MEDICAL & SURGICAL ENVIRONMENTS (I)

Why should common three layer medical face masks, grade IIR, evaluated under EN14683:2016 Standard only, NOT be used during surgical procedures in operating theatres or other medical examinations and settings?

- The commonly known three layer medical or surgical face mask, even if IIR graded, reaching a bacterial filtration superior to 98% and being compliant with ISO 22609 splash resistance requirements, when used by doctors, their assistants and other health care professionals is only offering limited protection to patients undergoing surgical interventions or during examinations and very low wearer protection, due to the fact that these models are not adapted to the wearers face and therefore showing a high leakage allowing potential infectious agents being transmitted both ways, from doctors to patients and vice versa.

Conclusion: Significant risk of mutual contagion with infectious agents

USAGE RECOMMENDATION FOR MEDICAL & SURGICAL ENVIRONMENTS (II)

Why should common particle filtering half masks, grade FFP2 or FFP3, evaluated under EN 149:2001 Standard only, with or without valve, NOT be used during surgical procedures in operating theatres or other medical examinations and settings?

- Common particle filtering FFP2 or FFP3 half masks generally protect doctors and healthcare professionals as wearer and also their patients during surgical interventions and medical examinations. However, under EN149:2001 Standard, bacterial filtration is not tested, nor evaluated. And the penetration test parameters and method (penetration tested with staphylococcus aurous bacteria) of EN 14683:2019 Standard differs from particle filtration testing (Na CL and Paraffin Oil) performed under EN 149:2001 Standard.
- Splash resistance against blood and body fluids under synthetic blood pressure is not examined
- Examination of microbial cleanliness under EN ISO 11373-1 is not performed, which means in particular, the presence or amount of micro-organisms on the inner masks surface has not been determined and the masks surface could be contaminated by micro-organism germs, which the wearer would then necessarily inhale or be in touch with. Neither the Bio-compatibility (Skin irritability, etc.) of the mask material is tested in accordance with EN ISO 10993-5 / 10
- Breathing resistance is tested under the parameters and methods of FFP Masks under EN149:2001 Standard and not under EN 14683:2019 medical standard (Breathability differential pressure test). Both methods are of complete different nature and Filtering Face Piece Half Masks, especially FFP2 and FFP3 grades, do usually NOT fulfil the breathability requirements of medical Standard EN 14683:2019, Annex C., as medical and surgical masks require a high level of breathability, which allows doctors and healthcare professionals to breath easier and concentrate better on their tasks, especially during interventions and examinations. FFP2 and FFP3 masks do usually not fulfil the medical breathability requirements.
- FFP masks with exhalation valve do not comply with medical standards, as patients would be exposed to potential contagion with infectious agents.

USAGE RECOMMENDATION FOR MEDICAL & SURGICAL ENVIRONMENTS (III)

Why <u>should</u> "Easy Breathing Protective Surgical Respirators Grade", evaluated under Dual Standard EN 149 : 2001 and EN 14683 : 2019, including Annex C for breathability-differential pressure, <u>BE</u> used during surgical procedures in operating theatres or other medical examinations and settings?

- A Protective Surgical Respirator Grade FFP2/IR evaluated as "easy breathing model" offers optimized breathability to doctors and all kind of healthcare professionals while performing surgical interventions and medical examinations, avoiding a possible leak of concentration due to reduced oxygen supply.
- Evaluation of Bacterial Filtration Efficiency and Particle Filtration Efficiency is performed, under the Standards of both MDD 93/42 EEC & MDR (EU) 2017/745 and PPE Regulation (EU) 2016/425
- Evaluation of Splash resistance against blood and body fluids is carried out.
- Bio Burden and Bio Compatibility are tested and the respirator, according to its medical certification, fulfils hygienic standard requirements and avoid skin irritations .
- The Respirator is adapted to the face minimizing the inward leakage of air flow, in accordance with the requirements of EN 149:2001, offering an optimized general protection level.

INNOVATIVE SOLUTION FOR PROTECTIVE MEDICAL & SURGICAL REQUIREMENTS

TEMRA MASK DUAL

Since more than a decade, companies of Temra® International are globally supplying essential raw materials to diverse industries, including the medical segment. In cooperation with its affiliates globally, Temra® International is manufacturing medical devices, especially medical and protective face masks and has established itself as solid and reliable supplier for governments and health institutions in Europe during times of pandemic crisis, being registered as medical device manufacturer at EUDAMED of the European Union and the Federal Institute of Drugs and Medical Devices of Germany (BfArM), as well as the Maltese Medicine Authorities.

Our company policy has always been to constantly grow and improve ourselves as regards every aspect of our business areas, with special emphasis to the supply of products which have become essential to health care professionals and related operators, such as protective surgical respirators.

Over several months our engineers have been dedicating special efforts towards the optimization of the raw material, design and composition of protective surgical respirator models which today reached to make a difference in health protection and whose results have been recently certified.

Temra Mask Dual Models, on the basis of optimization of its breathability and simultaneous reinforcement of its particle, viral and bacterial filtration and general protection level, have been launched as innovative solution to increasing breathing comfort, while entirely complying with both Standards EN 149:2001 for personal protective equipment and EN 14683:2019 for medical devices, including Annex C for breathability differential pressure, ISO 22609 for splash resistance, EN ISO 10993-5 for biological cleanliness and EN ISO 10993-5 /10 for biocompatibility.

ACCREDITATIONS & REGISTRATIONS
TEMRA MASK DUAL

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

ISO:	**22609**
EN ISO:	**11373-1**
EN ISO:	**10993-5**
EN ISO:	**10993-10**
ISO:	**9001:2005**
ISO:	**13485:2016**

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QCCSS Certification Services Limited
(European Union Notified Body Nº 2834, Ireland)

TÜV Rheinland®
(European Union Notified Body Nº 0197, Germany)

HYGCEN Austria GmbH
(Certification Body for Medical Devices - EN ISO 17025, Austria)

EUDAMED – European Databank on Medical Devices
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EUDAMED
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TEMRA MASK DUAL
EASY BREATHING FFP2 NR /IIR
PROTECTIVE SURGICAL RESPIRATORS

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PSM01	PSM02	PSM03
		

Article reference:	PSM01	PSM02	PSM03
Model:	Protective Surgical (Folding)		Protective Surgical (Flat Fold)
Category, Regulations and Directive:	Regulation (EU) 2016/425 for Personal Protective Equipment Medical Device Directive 93/42 EEC Regulation (EU) 2017/745 for Medical Devices		
Norm and Classification:	EN149:2001+A1:2009 EN14683:2009+AC:2019 FFP2/NR / IIR		
Filtration Efficiency according to Norm:	PFE ≥ 94% BFE ≥ 98%		
General Protection Level:	GPL ≥ 92%		
Filtration and Protection Level Temra:	PFE > 98%, BFE > 99%, GSL > 95%		
Material:	Non-woven fabric, melt blown polypropylene, hot air cotton, elastic tie-on or ear loops		
Breathability Medical Standard and Temra:	< 60 Pa/cm2		
Size:	16cm x 10.5cm		20,5cm x 8,5cm
Packaging:	Individual plastic bags		
Units per Box:	10		20

Further approved requirements: Breathing Resistance, Splash Resistance, Bi- Burden, Biocompatibility, Skin Compatibility, Flammability, Carbon Dioxide content of Inhalation air, Head harness and Field of Vision

TEMRA MASK DUAL
EEASY BREATHING – FFP3 NR / IIR
ULTRA PROTECTIVE SURGICAL MASK

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UPSM01

UPSM02

Article Reference:	UPSM01	UPSM02
Model:	Ultra Protective Surgical (CUP)	Ultra Protective Surgical (Folding)
Category, Regulations and Directive:	Regulation (EU) 2016/425 for Personal Protective Equipment Medical Device Directive 93/42 EEC Regulation (EU) 2017/745 for Medical Devices	
Norm and Classification:	EN149:2001+A1:2009 EN14683:2009+AC:2019 FFP3 / IIR	
Filtration Efficiency according to Norm:	PFE > 99% BFE > 98%	
General Protection Level:	GPL > 98%	
Filtration and Protection Level Temra:	PFE > 99%, BFE > 99%, GSL > 98%	
Material:	Non woven, melt blown polypropylene, hot air cotton, elastic head ties	
Breathability Medical Standard and Temra:	< 60 Pa/cm2	
Size:	13cm x 12cm	16cm x 10,5cm
Packaging:	10 units plastic bag	Individual plastic bags
Units per Box:	20	10

Further approved requirements: Breathing Resistance, Splash Resistance, Bi- Burden, Biocompatibility, Skin Compatibility, Flammability, Carbon Dioxide content of Inhalation air, Head Harness and Field of Vision