



2868-10SU SAFE+MASK® PREMIUM NORMASKIN / Type II with ties Medical Device, Class I

FEATURES & BENEFITS

- High filtration with filter media (polypropylene)
- Ties and edges in thermobonded nonwoven, very soft
- Anatomic folding limiting inward leakage
- Integrated anti-fog nose piece
- Filter without micro glass
- Production in ISO 8 clean room (particle and microbiological control)

Recommended use:

- Use by operating room personnel for surgeries, without risk identified for the wearer (projection of biological fluids)
- Suited to long time surgical operations
- If mask is dirty during operation, therefore change it



PRODUCT DETAILS

Product name:	Safe+Mask® Premium NormaSkin – Type II with ties
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	PP Complex (Meltblown + Spunbond)
Link:	Ties
Colour:	Green
Size:	95 x 175 mm (± 5 mm)
Unit weight:	3,2 g (± 10%)
Packaging:	Bag of 100 individual polybags
Origin:	France



Filtration and Comfort Information - NF EN 14683:2014 Type II

Measurements done by NELSON Laboratory (report available on request)

TEST	Required level	Laboratory	Report number	Date of Report	Average	Minimum value	Maximum value
Bacterial Filtration Efficiency: BFE (%)	98	NELSON	1033927-S01	16/04/2018	98,66	98,2	99,0
DELTA P (Pa/cm²)	29,4	NELSON	1033927-S01	16/04/2018	16,34	15,6	17,5
PFE PARTICULE 0,1µm (%)		NELSON	614275	16/01/2012	98,96	98,9	99,0
Using time efficiency: BFE		NELSON	1033927-S01	16/04/2018	4H: BFE = 98,20%		

Manufacturing Microbiological Information (by MICROSEPT Laboratory)

Bioburden evaluation meets the requirements of EN 14683: 2014 and NF EN 11737: 2006
 Additional microbiological controls: ASR, E.Coli, Staphylococcus, on request

Biological Evaluation - NF EN 14683:2014

	Standard	Required level	Laboratory	Report number	Date of Report	Results
Intracutaneous irritation test	ISO 10993-10	non irritation	NAMSA	231037	21/06/2017	non irritation
Cytotoxicity	ISO 10993-5	no cytotoxicity	NELSON	1030858-S01	22/03/2018	no cytotoxicity
Sensitization	ISO 10993-10 and -10A	topical application: no sensitization	NAMSA	231038	19/07/2017	topical application: no sensitization
		intradermal injection: no sensitization				intradermal injection: no sensitization

CERTIFICATION & STANDARDS

In accordance with requirements of medical devices Dir.93/42/EEC modified by Dir.2007/47/EC

Manufactured under ISO 13485 certified quality system.

In conformity with the relevant harmonized standard EN 14683 and EN ISO 14971

STORAGE CONDITIONS

Normal conditions of conservation & storage: not to be exposed to moisture and sun, must be stored at a temperature between 5°C and 40°C

Shelf life of the product: 5 years

LOGISTICAL INFORMATION



Outer case specifications

Inner case specifications

Item	Size mm	Gross weight kg	QTY/ pallet	QTY
2868-10SU	295 x 260 x 215	1,0	108 cartons (9 layers of 12 cartons)	2 bags of 100 individual polybags



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