



2860-B-30 SAFE+MASK® NORMASKIN
2860-G-30 Medical mask 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)
- If mask is dirty during operation, therefore change it



PRODUCT DETAILS

Product name:	MEDICOM - SafeMask NormaSkin - Mask - Type II
Product type:	Single use, non-sterile
Inner layer:	White Hypoallergenic Thermobond polypropylene
Filter:	Meltblown polypropylene
Outer layer:	Spunbond polypropylene
Link:	Ties
Packaging:	Box of 50 units
Origin :	France

Item	Colour	Size (± 5 mm)	Unit weight (± 10%)
2865-10	Blue 	95 x 175 mm	3,2 g
2868-10	Green 	95 x 175 mm	3,2 g



Filtration and Comfort Information - NF EN 14683:2019

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	1250735-S01	16/12/2019	98,8	98,6	99,2
DELTA P (Pa/cm ²)	≤ 40	NELSON	1250735-S01	16/12/2019	23,4	22,6	24,3

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

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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 European Regulation 2017/745 relative to Medical Devices.
 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	Size mm	QTY
2860-B-30	333 x 300 x 228	1,6	72 cartons	210 x 104 x 140	6 boxes of 50 pieces
2860-G-30		1,6	(8 layers of 4 cartons + 5 layers of 8 cartons)		



EAN Codes

Item	Outer case	Inner case
2860-B-30	3 662 036 014 214	3 662 036 014 207
2860-G-30	3 662 036 014 290	3 662 036 014 283

