Technical Data Sheet

2119BV

TYPE IIR MEDICAL MASK WITH EARLOOPS

Medical Device Class I

PRODUCT DESCRIPTION

Product name: Mask#53A

Product type: Single use, non sterile Inner layer: Spunbond polypropylène Filter: Meltblown polypropylène Outer layer: Spunbond polypropylène

Links: **Earloops**

Dimension: 95 mm (± 5 mm) x 175 mm (± 7 mm) Packaging: 10 x dispenser boxes of 50 masks

Origin: China





















Filtration and Comfort Information- NF EN 14683:2019 Type IIR

TEST	REQUIRED LEVEL	LABORATORY	REPORT NUMBER	DATE OF REPORT	AVERAGE	MINIMUM VALUE	MAXIMUM VALUE
BACTERIAL FILTRATION EFFIENCY: BFE (%)	≥ 98	NELSON	1320119-501	18/08/2020	99,5	99,3	99,7
DELTA P (Pa/cm²)	< 60	NELSON	1320119-S01	18/08/2020	47,4	44,9	49,3
SPLASH RESISTANCE (kPa)	≥ 16	NELSON	1320120-S01	06/08/2020		PASS	

PRECAUTIONS

The mask must be used on intact skin only.

Re-use or extended use may lead to infection or cross-contamination.

Please refer to your national legislation on the subject of disposal of this product once it has been used.

CERTIFICATION & STANDARDS

Complies with the requirements of Regulation (EU) 2017/745 relating to Medical Devices.

Complies with applicable harmonized standards EN 14683.

Manufactured under an ISO 13485 certified system.

STORAGE

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

Product life: 3 years

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LOGISTICS



Inner box

Item	Size mm	Gross weight	QTY/ pallet	Size QTY
2119BV	495 x 210 x 215	2 kg	72	103 x 103 x 215 10 boxes of 50 pieces

EAN codes

Item	Outer case	Dispenser box		
2119BV	8 718 007 913 903	8 718 007 913 910		