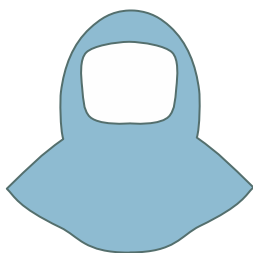


PRODUCT DATA SHEET



Total Healthcare Innovation GmbH

REF 80200 / ViVi® HOOD



SHORT DESCRIPTION

Sterile stand-alone head cover with transparent face-shield and air filtration feature.

INTENDED USE

The ViVi® Hood as component of the ViVi® System is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms.

GENERAL PRODUCT CHARACTERISTICS

Product Name	ViVi® HOOD
Article Number	80200
Color	Blue hood, white filter
Weight	92 g (typical)
Sterilization Method	Ethylene Oxide
Country of Origin	Turkey

PRODUCT DIMENSIONS

Overall Dimensions (H/W)	900 / 870 mm
Sizes	One size fits all
Face Shield Dimensions (H/W)	200 / 340 mm
Field of View	> 180°

HOOD MATERIAL (color: blue, breathable viral barrier)

Characteristics	Performance	Test Standard
Material Composition	Tri-laminate polypropylene outer layers and breathable film	
Basis weight	68 g/m ²	ASTM D3776
Dry Mullen Burst strength	2750 g/cm ²	ASTM D 4533-91
Dry tensile strength (MD/CD)	2440/1190 N/m	EN29073-3
MVTR	1300 g/m ² /day	ASTM E-96 (B)
Flammability	Class 1	16 CFR 1610.4

MVTR ... Moisture vapor transmission rate at 32°C, 50% RH

FILTER MATERIAL (color: white, breathing air ventilation)

Characteristics	Performance	Test Standard
Material Composition	Two layers of 100% Polypropylene SB Nonwoven fabric	
Basis weight	30 g/m ² , 15 g/m ²	ASTM D3776
Tensile strength 30/15g (MD/CD)	81/31 N/5cm (MD) 41/25 N/5cm (CD)	EN29073-3
Elongation @ break 30/15g (MD/CD)	90/58 % (MD) 78/63 % (CD)	EN29073-3
Flammability	Class 1	16 CFR 1610.4

MD ... machine direction

CD ... cross direction

TRANSPARENT FACE SHIELD MATERIAL

Characteristics	Performance	Test Standard
Material Composition	Transparent polycarbonate film	
Thickness	375 µm	
Density	1,2 g/cm ³	ISO 1183
Haze	< 0,5 %	ASTM D1003
Light Transmission	89 %	ASTM D1003
Tensile Strength	60 MPa	ISO 527
Bend Strength	91 MPa	ISO 187
Dielectric Constant	3	-
Surface resistivity	1.00 ⁺¹⁶ Ω/sq.	IEC 60093
Volume resistivity	1.00 ⁺¹⁷ Ω-cm	IEC 60093
Flammability	V-2/ VTM-2	E249605
Optical Quality	Class 1	EN 166 cl. 7.1.2.1

PERFORMANCE DATA – Personal Protective Equipment

The product is in compliance with the requirements defined by the harmonized standard EN 166:2001 - Personal Eye Protection and does offer protection against:

- High speed particles (45 m/s) – low energy impact
- Splashes of liquids

This product is not intended to be used as a respiratory protection device.

PERFORMANCE DATA – Medical Device

The hood is intended to act as sterile liquid barrier face shield. No performance standards are defined for hoods in medical applications, however, standards for surgical gowns have been used to define design requirements for the hood. These standards are ASTM 2407-06 (FDA) and EN 13795 (CE).

The barrier performance of the hood material (blue) in its role as barrier does comply with applicable requirements defined by:

- ASTM F2407-06 (incl. AAMI PB70 – Level 4 – critical zone)
- EN 13795 – level 'high performance – critical zone'

Characteristics	Performance	Test Standard
Resistance to viral penetration	Pass AQL 4.0 (HM)	ASTM F1671
Resistance to microbial penetration - wet	IB 6.0 (HM)	EN 22610
Resistance to microbial penetration - dry	≤ 300 CFU (HM)	EN 22612
Resistance to liquid penetration	≥ 100cm H ₂ O (HM)	EN 20811
Biocompatibility – skin irritation	Pass criteria for surface device/ breached or compromised skin, limited exposure acc. ISO 10993	
Biocompatibility – EO Residuals	≤ 10µg/cm ²	ISO 10993-7
Sterility	SAL 10 ⁻⁶ (acc. EN 556-1) achieved through a validated sterilization process compliant to ISO 11135-1	
Flammability	Class 1	16 CFR Part 1610
Particle emission rate	≤ 4.0 log ₁₀	ISO 9073-10
Cleanliness – particulate matter	IPM ≤ 3,5	ISO 9073-10
Bacterial filtration efficiency	> 99,999% (HM) 25-30% (FM)	ASTM F2101-07

HM ... Hood material (blue)

FM ... Filter material (white)

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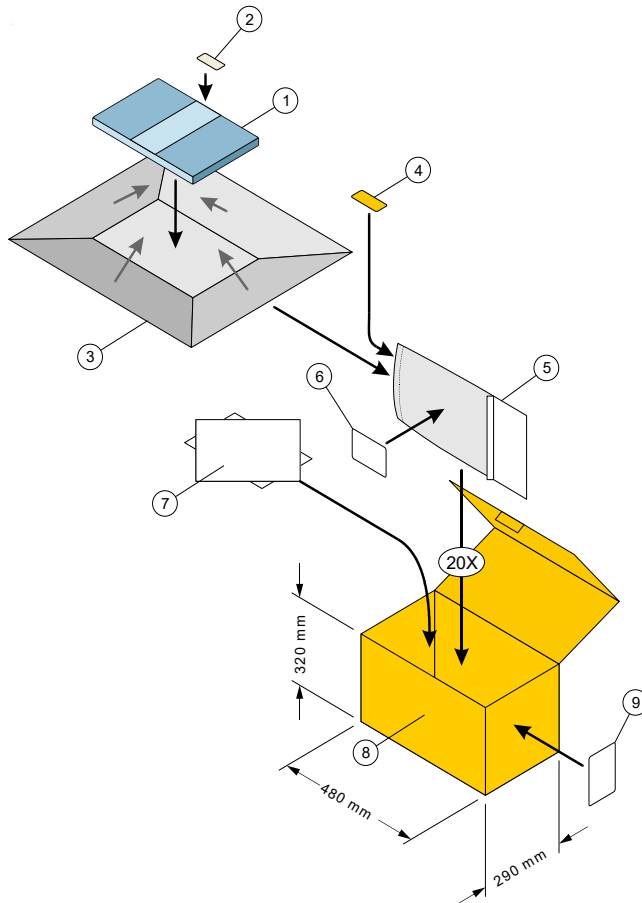


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PACKAGING SPECIFICATION

Storage Temperature	≤ 30 °C
Transport Temperature	≤ 49 °C
Shelf Life	3 years



pos	description	Qty (SBS)	Qty (box)	material	remarks
1	PRODUCT	1	20		
2	EN166 Sticker (PPE)	1	20	PE	pos: on lens
3	Wrapping paper	1	20	paper	
4	ETO indicator strip	1 in 20	1	acc. manual	
5	SBS (Polyester-Tyvek header bag)	1	20	PE/ Tyvek	300x450 mm
6	SBS label	1	20	Polyester/4 peel-off segments	
7	Instruction for Use		1	Paper	
8	protective packaging (box)		1	double corrugated carton, no printing	480x290x320 mm
9	box label		1	Polyester/paper	



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