

# TECHNICAL DOCUMENT

### Description

#### Blue

44749 BASICS\* Blue Nitrile - XS  
44750 BASICS\* Blue Nitrile - S  
44751 BASICS\* Blue Nitrile - M  
44752 BASICS\* Blue Nitrile - L  
44753 BASICS\* Blue Nitrile - XL

#### White

44740 BASICS\* White Nitrile - XS  
44741 BASICS\* White Nitrile - S  
44742 BASICS\* White Nitrile - M  
44743 BASICS\* White Nitrile - L  
44744 BASICS\* White Nitrile - XL



Non-powdered, textured fingertips, ambidextrous, single use. Color: Blue, White.

### Dimensions:

	Palm width	Length
Extra Small (XS)	75 mm	> 240 mm
Small (S)	85 mm	> 240 mm
Medium (M)	95 mm	> 240 mm
Large (L)	110 mm	> 240 mm
Extra Large (XL)	120 mm	> 240 mm

Properties:	HALYARD (Minimum Results/Specification Target)	EN/ ASTM requirement/Test Method
Median force at break before aging (Newton)	6.5 N	EN 455-2: 6N
Median force at break after aging (Newton)	6.5 N	EN 455-2: 6N
Residual powder mg/glove	2.0 mg (3x rinsed)	EN 455-3/ ISO 21171: <2.0 mg
Material Thickness (double wall)	Thickness middle finger: 0.08 mm Thickness palm: 0.055 mm Thickness cuff: 0.045 mm	--
Freedom of pinholes	1.5 AQL	EN 455-1: 1.5 AQL

### Indication

To protect patient and user from cross-contamination.

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Halyard gloves are tested by accredited independent laboratories: Akron Rubber & Development Lab (US), Eurofins Product Testing A/S (Belgium), Centexbel (Belgium). O&M Halyard is a global company that adheres to the regulatory rules and clearance requirements specific to each country where its products are registered and utilized.

Counter indication

Not intended for applications involving direct exposure to harsh chemicals, where heavy duty industrial gloves are required.

Main Materials

Base material: Nitrile Butadiene.  
Accelerators: ZDBC (ZINC DIBUTYLDITHIOCARBAMATE).  
Not intentionally formulated or treated with any of the following: Bisphenol A, colophony (rosin), natural rubber latex, brominated flame retardants, phthalates (DBP, BBP, DEHP, DMEP, DNOP, DPP, DIPP, DIDP, DINP).

Skin Friendly

Biocompatibility testing – Medical Devices	HALYARD
Biocompatibility testing in accordance with the ISO 10993-1 <ul style="list-style-type: none"><li>ISO 10993-10 (sensitization)</li><li>ISO 10993-10 (irritation)</li></ul>	Pass

Residual Chemicals

High Pressure liquid Chromatography (HPLC)	HALYARD
Measure the type and amount of residual chemicals left on the glove. Lower levels of residual chemicals decrease the risk of developing irritant and Type IV reactions.	Rinsed 3x to reduce harmful chemicals to below detectable levels. ZDBC (ZINC DIBUTYLDITHIOCARBAMATE)

Sterilization

Products are non-sterile.

Packaging

References 44749, 44750, 44751, 44752, 44740, 44741, 44742, 44743:  
Shipping case of 2000 units.  
10 dispenser boxes of 200 units in each shipping case.

Reference 44753, 44744: Shipping case of 1700 units.  
10 dispenser boxes of 170 units in each shipping case.

Bar coding: GS1-128 symbology, linear, on shipping case and dispenser box.

Dimensions	Length	Breadth	Height
Dispenser Box (mm)	245	128	80
Shipping Case (mm)	364.972	259.003	254.99

EAN

Item	Description	AUn	EAN/UPC
44740	BASICS* White Nitrile Exam Gloves XS	Sell Unit Package	30680651447402

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Item	Description	AUn	EAN/UPC
44740	BASICS* White Nitrile Exam Gloves XS	Inner Package	20680651447405
44741	BASICS* White Nitrile Exam Gloves S	Sell Unit Package	30680651447419
44741	BASICS* White Nitrile Exam Gloves S	Inner Package	20680651447412
44742	BASICS* White Nitrile Exam Gloves M	Sell Unit Package	30680651447426
44742	BASICS* White Nitrile Exam Gloves M	Inner Package	20680651447429
44743	BASICS* White Nitrile Exam Gloves L	Sell Unit Package	30680651447433
44743	BASICS* White Nitrile Exam Gloves L	Inner Package	20680651447436
44744	BASICS* White Nitrile Exam Gloves XL	Sell Unit Package	30680651447440
44744	BASICS* White Nitrile Exam Gloves XL	Inner Package	20680651447443
44749	BASICS* Blue Nitrile Exam Gloves XS	Sell Unit Package	30680651447495
44749	BASICS* Blue Nitrile Exam Gloves XS	Inner Package	20680651447498
44750	BASICS* Blue Nitrile Exam Gloves S	Sell Unit Package	30680651447501
44750	BASICS* Blue Nitrile Exam Gloves S	Inner Package	20680651447504
44751	BASICS* Blue Nitrile Exam Gloves M	Sell Unit Package	30680651447518
44751	BASICS* Blue Nitrile Exam Gloves M	Inner Package	20680651447511
44752	BASICS* Blue Nitrile Exam Gloves L	Sell Unit Package	30680651447525
44752	BASICS* Blue Nitrile Exam Gloves L	Inner Package	20680651447528
44753	BASICS* Blue Nitrile Exam Gloves XL	Sell Unit Package	30680651447532
44753	BASICS* Blue Nitrile Exam Gloves XL	Inner Package	20680651447535

Manufacturing

Products are manufactured in Malaysia. The quality system of the manufacturing sites are ISO 13485 and ISO 9001 compliant.

Regulatory information

- Product CE marked as per Regulation (EU) 2017/745 on Medical Devices. Class of the device: I.
- Product CE marked as per (EU) 2016/425 regulation on Personal Protective Equipment. Class of the equipment: PPE Category III
- Comply with EN 455-1, EN 455-2, EN 455-3, EN 455-4
- Comply with EN 21420
- Comply with EN ISO 374-1, EN 374-2, EN 374-4, EN 374-5, EN 16604, EN 16523-1
- Comply with ISO 16604
- Approved for Food Contact as per Regulation 1935/2004 and 10/2011.

Medical Device Class I



AQL	HALYARD	EN 455-1 requirement
Freedom from pinholes	1.5	1.5

EN ISO 374-5 Microorganism risks	HALYARD
Resistance to bacteria and fungi	Pass
Resistance to virus	Pass (ISO 16604)

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- **EN 374-1 Type C (K) - EN 16523-1**

Chemical	Permeation Test		Degradation Test
	EN 16523-1:2015+A1:2018		EN ISO 374-4:2019
	Minimum Breakthrough Time (min)	Performance Level	Degradation (%)
Sodium hydroxide, 40% (K)	>480	6	-54.8

Performance levels according to EN ISO 374-1:2016 +A1:2018	1	2	3	4	5	6
Measured breakthrough times (mins)	> 10	> 30	> 60	> 120	> 240	> 480

Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemical.  
 NOTE: Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

### Storage

Store in a dry and cool place, away from intense sources of heat and sources of radiation.  
 Keep as much as practicably possible in its shipper box.

### Shelf life

3 years, from the date of manufacture.

### Chemotherapy/Chemicals

At O&M Halyard, we seek to constantly improve upon the quality of healthcare products and services available in the marketplace. We strive to deliver clinically superior products with remarkable service to improve the wellbeing of the people we touch every day. In accordance with this vision, we want to inform our customers of additional chemical and chemotherapy drug testing performed on our **Basic\* Free Nitrile Exam Gloves**. In the US, the Food and Drug Administration requires submission and clearance of a premarket notification for medical exam gloves that are intended for use with chemotherapy drugs and requires glove products to be labeled with drugs tested and breakthrough times. Package labeling for Halyard exam gloves sold in the US meet this labeling requirement. Although additional chemotherapy drug and chemical testing is not required, Halyard believes the more informed our customers are, the better they will be able to understand the appropriate use of our products. The following chemotherapy drugs and chemicals have been tested according to EN374-1 (EN 16523-1 where applicable), ASTM D6978 (chemotherapy drugs) and ASTM F739 (chemicals). This data is provided for your information but is not intended to expand the intended use of the products beyond the scope of what has been cleared by the FDA or covered by the safety and performance requirements of the CE certification and European harmonized standards.

### Chemical Testing Information – ASTM F739/EN 374-1: EN 16523-1 (where applicable)





Chemicals Tested	CAS #	Test Method	Breakthrough time (minutes) Blue Basics*
Ethidium Bromide (1%)	1239-45-8	EN 16523-1	>480
Hydrochloric Acid, 30%	7647-01-0	EN 16523-1	240
Sodium Hydroxide (40%)	1310-73-2	EN 16523-1	> 480
Sulfuric Acid (50%)	7664-93-9	EN 16523-1	> 480
Isopropyl Alcohol, (30%)	67-63-0	EN 16523-1	33.6
Isopropyl Alcohol, (50%)	67-63-0	EN 16523-1	26.1

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Chemicals Tested	CAS #	Test Method	Breakthrough time (minutes) Blue Basics*
Ethanol (70%)	64-17-5	EN 16523-1	17
Formaldehyde (37%)	50-00-0	EN 16523-1	> 480

Sustainability

ISO 14001:2015 - Environmental management systems	
Patented nitrile exam glove dispensers and cartons, made with up to 95% recycled material.	<p>PACKAGING MADE WITH UP TO 95% RECYCLED MATERIAL</p> 
<p>The patented SMARTPULL* Dispenser has been proven to reduce glove waste by 38.2%. By ensuring smooth, single-glove dispensing, it optimizes glove utilization, helping healthcare facilities maintain hygiene standards while minimizing waste. Packed up to 200 gloves per dispensers the SMARTPULL* dispenser reduces excessive use of packaging materials, energy, storage and transportation making it an excellent option and more sustainable solution for your facility. †</p> <ul style="list-style-type: none"><li>• Reduce glove consumption</li><li>• Reduce glove waste</li><li>• Reduced use of materials, energy and transport</li></ul> <p>† Compared to standard 100 count boxes</p>	<p>38.2% WASTE REDUCTION</p> 
<p>Economical packaging</p> <p>Feature increased pack sizes of up to 2000 eaches per case, saving storage space†</p> <p>† Compared to standard 100 count boxes</p>	<p>IDEAL FOR STOCKPILING – SAVE UP TO 67% STORAGE SPACE</p> 

Our Commitment to you

Better Infection Prevention

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