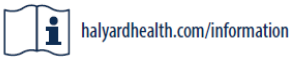
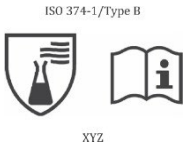
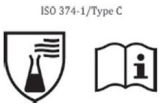
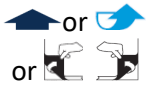
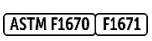
Symbols Glossary

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
	European Conformity	Indicates that the product complies with the requirements of the relevant European health, safety and environmental protection legislation	MDD 93/42/EEC[1] / ANNEX XII MDR 2017/745[2] / ANNEX V
	Manufacturer	Indicates the Medical Device Manufacturer	BS EN ISO 15223-1[3] / 5.1.1
	Manufacturer	Indicates the Medical Device Manufacturer in situations where the background print color is dark	[10]
	Authorized representative in the European Community	Indicates the authorized representative in the European Community	BS EN ISO 15223-1[3] / 5.1.2
	Date of Manufacture	Indicates the date when the medical device was manufactured	BS EN ISO 15223-1[3] / 5.1.3
	Use By	Indicates the date after which the medical device is not to be used	BS EN ISO 15223-1[3] / 5.1.4
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	BS EN ISO 15223-1[3] / 5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	BS EN ISO 15223-1[3] / 5.1.6
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	BS EN ISO 15223-1[3] / 5.2.3
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	BS EN ISO 15223-1[3] / 5.2.4
	Do not resterilize	Indicates a medical device is not to be resterilized	BS EN ISO 15223-1[3] / 5.2.6
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process	BS EN ISO 15223-1[3] / 5.2.7
	Do not use if packaging is damaged	Indicates a medical device should not be used if the package has been damaged or opened	BS EN ISO 15223-1[3] / 5.2.8

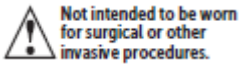
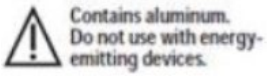
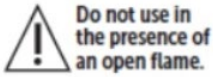
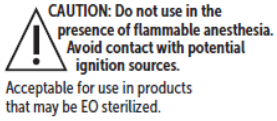
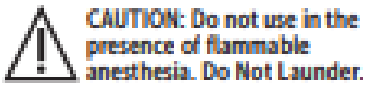
SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
	Keep away from sunlight	Indicates a medical device that needs protection from light sources	BS EN ISO 15223-1[3] / 5.3.2
	Protect from heat and radioactive sources	Indicates a medical device that needs protection from heat and radioactive sources	BS EN ISO 15223-1[3] / 5.3.3
	Keep Dry	Indicates a medical device that needs to be protected from moisture	BS EN ISO 15223-1[3] / 5.3.4
	Keep Dry. Store in less than 85% humidity	Indicates humidity limits to which the medical device can be safely exposed	[10]
	Temperature Limit	Indicated the temperature limits to which the medical device can be safely exposed	BS EN ISO 15223-1[3] / 5.3.7
	Humidity limitations	Indicates the range of humidity to which the medical device can be safety exposed	BS EN ISO 15223-1[3] / 5.3.8
	Do not re-use	Indicates a medical device that is intended for one use, or for the use on a single patient during a single procedure	BS EN ISO 15223-1[3] / 5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	BS EN ISO 15223-1[3] / 5.4.3
	Consult Instructions for Use at halyardhealth.com/information	Indicates the need for the user to consult the instructions for use	BS EN ISO 15223-1[3] / 5.4.3, A.15
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot, for a variety of reasons, be presented on the medical device itself	BS EN ISO 15223-1[3] / 5.4.4
	Contains Phthalates - DEHP	Indicates medical device contains phthalates [DEHP Di(2-ethylexyl)]	BS EN 15986[4] / 4.2
	Does Not Contain Phthalates - DEHP	Indicates medical device does not contain Phthalates – DEHP [DEHP Di(2-ethylexyl)] as a plasticizer	[10]

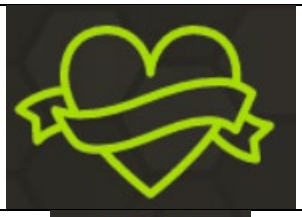
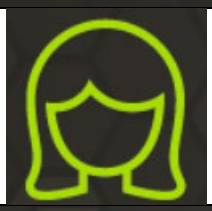
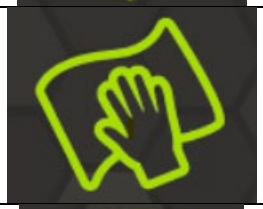
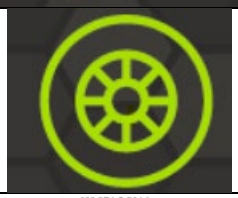
SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
	Magnetic Resonance (MR) Unsafe	Keep away from magnetic resonance imaging (MRI) equipment	ASTM F2502-13[5] / 7.3.3
	Chemical Protection Level	Indicates the product provides a Type B level of chemical permeation protection per EN ISO 374-1:2016+A1:2018. The three tested chemicals are identified by their code letter (XYZ) marked under the pictogram	EN ISO 374-1[6] / 6.3
	Chemical Protection Level	Indicates medical device provides a Type C level of chemical permeation protection	EN ISO 374-1[6] / 6.3
	Micro-organism protection – Protection Against Bacteria and Fungi	Indicates medical device protects the users against bacteria and fungi	EN ISO 374-5[7] / 6.2
	Food Contact Safe	Indicates that the medical device is safe for food contact	Regulation (EC) No 1935/2004[8] / ANNEX II
	Importer	Indicates the entity importing the medical device into the *European Union*	BS EN ISO 15223-1[3] / 5.1.8
	Single sterile barrier system with protective packaging inside	Indicates a single barrier system with protective packaging inside	BS EN ISO 15223-1[3] / 5.2.13
	Medical Device	Indicates the item is a medical device	BS EN ISO 15223-1[3] / 5.7.7
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information	BS EN ISO 15223-1[3] / 5.7.10
	Not made with natural rubber latex	Natural rubber latex was not used as a material in the manufacture of the product, product container, and/or packaging	Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex, Guidance for Industry and Food

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
			and Drug Administration Staff Document issued on: December 2, 2014
	Does not contain natural rubber latex	Indicates that the medical device does not contain natural rubber latex	BS EN ISO 15223-1[3] / 5.4.5
	Intended for use on children ages 3 and over	Indicates that the medical device should be worn only by children age 3 and over	10
	Pair of Gloves	Indicates that a pair of gloves (two) are provided as a base unit of use	10
	Single Glove	Indicates that one ambidextrous glove is provided as a base unit of use	10
	Dispose Properly	Dispose of in accordance with Local Authority Regulations	10
	Open Here	Indicates opening locations for sterile barrier packages	10
	Do not open with a sharp knife	Indicates that the package should not be opened with a sharp knife to avoid damaging the product inside the package	10
	AAMI Level 3	Indicates that the medical device meets the Level 3 performance requirements of ANSI/AAMI PB70	10
	AAMI Level 4	Indicates that the medical device meets the Level 4 performance requirements of ANSI/AAMI PB70	10
	ASTM 1670 and 1671 Testing	Indicates that the material used in the medical device has been tested and meets ASTM F1670 (Standard Test Method for resistance of materials used in protective clothing to penetration by synthetic blood) and ASTM	10

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
		F1671 (Standard Test Method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage as a test system)	
	EN 13795 Standard Performance	Indicates that the medical device meets the standard level performance requirements of EN 13795	10
	EN 13795 High Performance	Indicates that the medical device meets the high level performance requirements of EN 13795	10
	Wear printed side out	Indicates that the wearer should put face mask on with printed side out	10
	Place ear loops over ears	Indicates that wearer should place ear loops over ears to secure face mask to face	10
	Shape nose wire to face	Indicates that wearer should press on the malleable nose wire to shape the face mask to face for best fit	10
	Consult Declaration of Conformity	Indicates the need for the user to consult the Declaration of Conformity located at the referenced URL	10
	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	Indicates that the device is not intended to be used by a lay person	11
	Intertek Certification	Indicates that the device is certified and meets referenced standard	12
	Separate collection for waste of electrical and electronic equipment	Indicates separate collection for EEE	13
	Lithium Ion Battery Recycling	Indicates that the lithium ion battery should be recycled	14

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	BS EN ISO 15223-1[3] / 5.1.7
	Electrical Hazard	Indicates that there is a risk of electric shock	15
	Fuse	Indicates that the product has a neutral fuse	15
F3.15AH250	Fast Acting Fuse Rating	This product contains a fast acting fuse rated at 3.15A at 250V	15
	Atmospheric Pressure Limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	BS EN ISO 15223-1[3] / 5.3.9
	Acceptable Quality Limit for Freedom from Holes Testing – AQL 1.0	Indicates that this product exceeds AQL requirements *Medical gloves for single use – Part 1: Requirements and testing for freedom from holes*	10
	Acceptable Quality Limit for Freedom from Holes Testing – AQL 1.5	Indicates that this product meets AQL requirements per BS EN 455‑1 *Medical gloves for single use – Part 1: Requirements and testing for freedom from holes*	10
	Acceptable Quality Level, Performance Level, and Inspection Level for Water Leak Testing – AQL 0.65 Level 3 G1	Indicates that this product meets or exceeds AQL requirements per ISO 374-2 *Protective Gloves Against Dangerous Microorganisms – Part 2: Determination of resistance to penetration*	16
	Acceptance Quality Level, Performance Level, and Inspection Level for Water Leak Test – AQL 1.0 Level 2 G1	Indicates that this product meets or exceeds AQL requirements per ISO 374-2 *Protective Gloves Against Dangerous Microorganisms – Part 2: Determination of*	16

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
		resistance to penetration	
Medical Device Class I CE 2797 (PPE Cat. III)	Medical Device Class I, PPE Category III certified by BSI (CE 2797)	Indicates that this device is a Class I device under the Medical Device Regulation 2017/745 and the product is certified to the PPE Regulation 2016/425 by Notified Body 2797	10
	Single Patient – Multiple Use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient	10
	Not to be worn for surgical or invasive procedures	Indicates that the device should not be worn for surgical or other invasive procedures	10
	Contains aluminum. Do not use with energy-emitting devices.	Indicates medical device contains aluminum and should not be used with energy-emitting devices	10
	Do not use in the presence of an open flame.	Indicates the medical device should not be used in the presence of an open flame	10
	CAUTION: Do not use in the presence of flammable anesthesia. Avoid contact with potential ignition sources. Acceptable for use in products that may be EO sterilized.	Indicates the medical device should not be used in the presence flammable anesthesia and to avoid contact with potential ignition sources. Indicates the medical device may be used in products that may be sterilized by Ethylene Oxide.	10
	CAUTION: Do not use in the presence of flammable anesthesia. Do Not Launder.	Indicates the medical device should not be used in the presence flammable anesthesia and do not launder.	10
	Law Enforcement	Indicates the consumer glove may be used within law emforcement applications	10

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
	Tattoo & Piercing	Indicates the consumer glove may be used within tattoo and piercing applications	10
	Salons	Indicates the consumer glove may be used within salon applications	10
	Food Service	Indicates the consumer glove may be used within food service applications	10
	Cleaning	Indicates the consumer glove may be used within cleaning applications	10
	Automotive	Indicates the consumer glove may be used within automotive applications	10
	Micro-organism protection – Protection Against Bacteria, Fungi, and Viruses	Indicates medical device protects the users against bacteria, fungi, and viruses	EN ISO 374-5[7] / 6.2
	UK Declaration of Conformity	Indicates that the product is in conformity with the relevant statutory requirements applicable to the specific product, and that the issuer takes full responsibility for the product's compliance	UK Medical Devices (Amendment etc.) (EU Exit) Regulations
	Authorized representative in the Great Britain (UK Responsible Person)	Indicates the authorized representative in Great Britain	UK Medical Devices (Amendment etc.) (EU Exit) Regulations
	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland	Swiss Medical Devices Ordinance

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
CH REP	Authorized representative and importer in Switzerland	Indicates the authorized representative and the entity importing the medical device into Switzerland	Swiss Medical Devices Ordinance

Note: Symbols identified in the table for medical devices are also utilized for non-medical products (ie PPE, consumer products, etc.)

Number	Standard Reference	Standard Title
1	MDD 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
2	MDR 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
3	BS EN ISO 15223-1	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General Requirements
4	BS EN 15986	Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates
5	ASTM F2502-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
6	EN ISO 374-1	Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks; Amendment 1
7	EN ISO 374-5	Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks
8	Regulation (EC) No 1935/2004	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004
9	Directive 2009/48/EC	Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys
10		Symbols for which there is no normative standards reference
11	21 CFR 801.109	21 CFR § 801.109 - Prescription devices
12	Intertek Certification	Direct Imprint Labeling Guidelines by Intertek
13	Directive 2012/19/EU Annex IX	Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)
14	IEC 62902:2019	Secondary cells and batteries - Marking symbols for identification of their chemistry
15	IEC 60950-1	Information technology equipment — Safety — Part 1: General requirements
16	EN ISO 374-2	ISO 374-2 Protective Gloves Against Dangerous Microorganisms – Part 2: Determination of resistance to penetration