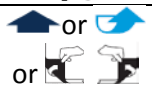
SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
CE	European Conformity	Indicates that the product complies with the requirements of the relevant European health, safety and environmental protection legislation	MDD 93/42/EEC[1] / ANNEX XII MDR 2017/745[2] / ANNEX V
	Manufacturer	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] / 5.1.4
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	BS EN ISO 15223-1[3] / 5.1.4
	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 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
	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

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
	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
	Caution	Indicates the need for the user to consult the instructions for ruse 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
	Magnetic Resonance (MR) Unsafe	Keep away from magnetic resonance imaging (MRI) equipment	ASTM F2502-13[5] / 7.3.3
	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	Indicates medical device protects the users against micro-organisms	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*	10
	Single sterile barrier system with protective packaging inside	Indicates a single barrier system with protective packaging inside	10
	Medical Device	Indicates the item is a medical device	10
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information	10
	Does not contain natural rubber latex	Indicates that the medical device does not contain natural rubber latex	10
	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 4	Indicates that the medical device meets the Level 4 performance requirements of ANSI/AAMI PB70	10

SYMBOL	SYMBOL TITLE	DESCRIPTION OF SYMBOL	STANDARD REFERENCE / CLAUSE
ASTM F1670 F1671	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 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)	10
EN 13795 Standard Performance	EN 13795 Standard Performance	Indicates that the medical device meets the standard level performance requirements of EN 13795	10
EN 13795 High Performance	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

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