Symbols Glossary

Explanation of the symbols used on Kuraray Noritake Dental's products labels and packaging.

Symbol	Title	Reference number	Description
Referenced standard: ISO 15223-1 Medical devices. Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements			
	Manufacturer	5.1.1	Indicates the medical device manufacturer
	Authorized representative	5.1.2	Indicates the authorized representative in the identified country or jurisdiction *The [XX] text of the symbol shall be replaced by either the two-letter country code or the three-letter country code defined in ISO 3166-1 or other text required by the authority having jurisdiction.
	Date of manufacture	5.1.3	Indicates the date when the medical device was manufactured
	Use-by date	5.1.4	Indicates the date after which the medical device is not to be used
	Batch code	5.1.5	Indicates the manufacture's batch code so that the batch or lot can be identified
	Catalogue number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Importer	5.1.8	Indicates the entity importing the medical device into the locale
	Non-sterile	5.2.7	Indicates a medical device that has not been subjected to a sterilization process

Symbol	Title	Reference number	Description
	Keep away from sunlight	5.3.2	Indicates a medical device that needs protection from light sources
	Temperature limit	5.3.7	Indicates the temperature limits to which the medical device can be safety exposed
	Do not re-use	5.4.2	Indicates a medical device that is intended for one single use only
	Consult instructions for use or consult electronic instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use
	Caution	5.4.4	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Medical device	5.7.7	Indicates the item is a medical device
	Unique device identifier	5.7.10	Indicates a carrier that contains unique device identifier information

Symbol	Title	Reference number	Description
Referenced standard: ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment			
	MR Conditional	Section 3.1 — Definition of "MR Conditional"	Indicates that the item has demonstrated safety in the MR environment within defined conditions, such as specified static magnetic field strength, spatial gradient, RF fields, or SAR limits, and may be used only when all stated conditions are met.
Referenced regulation: 21 CFR 801. 15(c)(1)(i)(F) and Federal Law (USA)restricts this device to sale by or on the order of a licensed physician (21 CFR 801.109(b)(1))			
Rx Only	Prescription Device Restriction Statement	-	Indicates that the medical device is restricted to use or sale under the order of a licensed healthcare practitioner