Symbols Glossary

Explanation of the Symbols Used on Dentsply Sirona Implants Labels and Packaging

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements			
SYMBOL	**TITLE**	**DESCRIPTION**	**REF NO.**
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. This symbol is accompanied by the name and address of the manufacturer.	5.1.1
	Authorized representative in the European Community	Indicates the authorized representative in the European Community This symbol is accompanied by the name and address of the authorized representative in the European Community.	5.1.2
	Date of manufacture	Indicates the date when the medical device was manufactured. Date format: YYYY-MM-DD	5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used. Date format: YYYY-MM-DD	5.1.4

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SYMBOL	**TITLE**	**DESCRIPTION**	**REF NO.**
	Batch code	Indicates the manufacturer’s batch code so that the batch or lot can be identified.	5.1.5
	Catalog number	Indicates the manufacturer’s catalog number so that the medical device can be identified.	5.1.6
	Serial number	Indicates the manufacturer’s serial number so that a specific medical device can be identified.	5.1.7
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3

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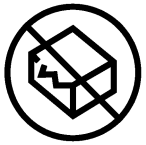
SYMBOL	**TITLE**	**DESCRIPTION**	**REF NO.**
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do not resterilize	Indicates a medical device that is not to be resterilized.	5.2.6
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8

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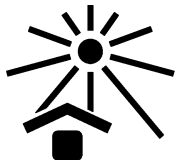
SYMBOL	**TITLE**	**DESCRIPTION**	**REF NO.**
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	5.3.2
	Keep dry	Indicates a medical device that needs to be protected from moisture.	5.3.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Do not re-use/ Single use/ Use only once	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2

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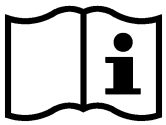
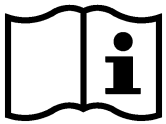
SYMBOL	**TITLE**	**DESCRIPTION**	**REF NO.**
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3
 **ifu.dentsplysirona.com**	Consult Instructions for Use or For Instructions for Use and Symbols Glossary refer to	Indicates the need for the user to consult the instructions for use and where the electronic instructions for use (eIFU) and symbols glossary can be found.	5.4.3
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that, for a variety of reasons, cannot be presented on the medical device itself.	5.4.4
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties	5.4.10

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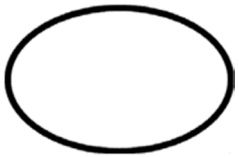
SYMBOL	**TITLE**	**DESCRIPTION**	**REF NO.**
	Single sterile barrier system	Indicates a single sterile barrier system	5.2.11
	Double sterile barrier system	Indicates two sterile barrier systems	5.2.12
	Importer	Indicates the entity importing the medical device into the locale	5.1.8
	Distributor	Indicates the entity distributing the medical device into the locale	5.1.9

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Other symbols and markings			
SYMBOL	**TITLE**	**DESCRIPTION**	**REFERENCE**
CE	Conformité Européenne or European Conformity	European conformity (CE) mark for Class I medical devices	European Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC) and Regulation (EU) 2017/745
CE 0123	Conformité Européenne or European Conformity	European conformity (CE) mark with Notified Body identification number for Class IIa, IIb, III medical devices Notified Body No. 0123: TÜV SÜD Product Service GmbH, Germany	European Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC) and Regulation (EU) 2017/745
Rx only	Prescription only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or physician.	Indicates that the product is a medical device as defined in 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)
	Russian certification symbol according to GOST	GOST is an acronym for "gosudarstvennyi standart", which means "state standard".	Russian State Standard

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Other symbols and markings			
SYMBOL	**TITLE**	**DESCRIPTION**	**REFERENCE**
	Medical Device	Indicates that the device is a medical device.	Requirement according to MDR 2017/745 Annex I, Chapter III, Article 23.2 (q)