



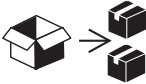





Explanation of non-harmonized symbols for IFUs and labels








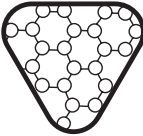
FOREWORD :





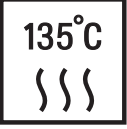



Non-harmonized symbols used for VDW products are covered herewith.









Harmonized symbols are part of ISO 15223, ISO 15223-1, IEC 60601-1 or WEEE Directive 2012/19/EU (e-waste guide).









	<p>Model number: Identifies the model number or type number of a product.</p>		<p>Medical device: Indicates the item is a medical device.</p>
	<p>Distributor: Identifies the distributor of a product. This symbol shall be used adjacent to the name and address of the distributor.</p>		<p>Positioning of Cell: Identifies the battery holder itself and the positioning of the cell(s) inside the battery holder.</p>
	<p>Importer: Identifies the importer name and physical address.</p>		<p>Fuse ratings: Indicates applicable fuse rates to the device.</p>
	<p>UDI: Identifies the UDI carrier when other carriers (or barcodes) are present.</p>		<p>Fuse: Identifies fuse boxes or their location.</p>
	<p>Country of manufacture: Identifies the country of manufacture of products.</p>		<p>IP code: Indicates the degrees of protection provided by an enclosure against access to hazardous parts, ingress of solid foreign objects, ingress of water and to give additional information in connection with such protection.</p>
	<p>Translation: Indicates the original medical device information has undergone a translation which supplements or replaces the original information.</p>		<p>Assortment: Identifies that the package includes an assortment of types or sizes.</p>









	Cannot be sold separately: Indicates items in package cannot be sold separately.
	Packaging unit: Indicates the number of pieces in the package.
	Repackaging: Identifies that a modification to the original medical device packaging configuration has occurred.
	Opened packages are not replaced: Indicates that, based on our returns policy, opened packages are not replaced
	Keep upright: Indicates the correct positioning of a package in transport and/or storage.
	Humidity measurement: Indicates the measurement of humidity.
	PCT Gost: Indicates the product complies to GOST-R regulations. Gost: Gosudarstvennyi standards or the Russian equivalent of ANSI.
	CSA Logo: Indicates product has been tested against applicable North American standards requirements. CSA: Canadian Standard Association.









	FCC Logo: Indicates Federal Communications Commission declaration of conformity.
	UL Symbol: Indicates product complies with UL (Underwriters Laboratories) standards for product safety.
	Inmetro: This symbol is only a placeholder. The correct symbol is to be provided with device registration National Institute of Metrology, Standardization and Industrial Quality, Brazil.
	Hazardous substances: Indicates a medical device that contains substances that can carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.
	Health hazard: Indicates acutely toxic (harmful) irritant to skin, eyes or respiratory tract. Skin ensitizer and hazardous to the ozone layer.
	Contains the presence of xxx: Indicates the equipment contains the identified product or substance. XXX here is variable and should be changed to the material name accordingly.
	CMR: Indicates a product contains CMR substances.
	Nanomaterial: Indicates a device that contains nanomaterials.




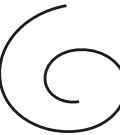


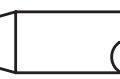

	<p>Professional Use: Indicates a product is not safe for use without a trained professional.</p>
	<p>Caution, hot surface: Indicates the marked item can be hot and should not be touched without taking care.</p>
	<p>Single patient -multiple use: Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.</p>
	<p>Use less than: Indicates the recommended number of times the product can be used less one (12 is an example only. If 12 is indicated in the symbol, it means the product cannot be used more than 11 times).</p>
	<p>Sterilizable up to the temperature specified: Indicates that the equipment can be sterilized to a maximum temperature as indicated.</p>
	<p>Sterilizable in a steam sterilizer (autoclave) at temperature specified: Indicates that the instrument is sterilizable in a steam sterilizer (autoclave) at the specified temperature.</p>
	<p>Do not sterilize: Indicates a medical device that can not be sterilized.</p>
	<p>Sterilized using Vaporized hydrogen peroxide: Indicates a medical device that has been sterilized using vaporized hydrogen peroxide.</p>

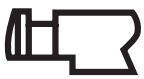
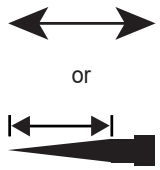

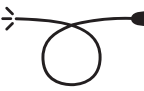

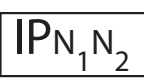


	<p>Thermal Disinfection: Indicates the instrument can be used with a washer-disinfector for thermal disinfection.</p>
	<p>Ultrasonic bath: Indicates the instrument can be cleaned in an ultrasonic bath.</p>
	<p>Double sterile barrier system: Indicates two sterile barrier systems.</p>
	<p>Single sterile barrier system: Indicates a single sterile barrier system.</p>
	<p>Single sterile barrier system with protective packaging inside: Indicates a single sterile barrier system with a protective packaging inside.</p>
	<p>Single sterile barrier system with protective packaging outside: Indicates a single sterile barrier system with a protective packaging outside.</p>
	<p>Not sterile: Indicates the product is not sterile.</p>
	<p>Gel: Indicates a product contains or presence of gel.</p>

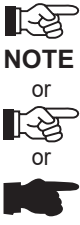

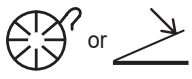




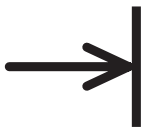
	Gutta Percha: Indicates a product contains or presence of gutta percha.
	MTA: Indicates a product contains or presence of mineral trioxide aggregate (MTA).
	Paper: Indicates a product contains or presence of paper (Paper Point).
	NiTi: Indicates a product contains or presence of Nitinol / Nickel titanium.
	M-Wire product: Indicates a product contains nickel titanium memory wire.
	Tungsten Carbide: Indicates a product contains or presence of tungsten carbide.
	Stainless Steel: Indicates a product contains or presence of stainless steel.
	Diamond: Indicates a product contains or presence of diamond.




	Chromium: Indicates a product contains or presence of chromium.
	Titanium: Indicates a product contains or presence of Titanium.
	Aluminum: Indicates a product contains or presence of Aluminum.
	Silicone: Indicates a product contains or presence of Silicone.
	Plastic: Indicates a product contains or presence of plastic.
	Fiberglass: Indicates a product contains or presence of Fiberglass.
	Root-canal sealer: Indicates a product contains or presence of sealer.
	Copper: Indicates a product contains or presence of Copper.

	Polyphenylene Sulphide: Indicates a product contains or presence of polyphenylene sulphide.
	Polyphenylsulfone: Indicates a product contains or presence of Polyphenylsulfone.
	RECIPROC: Indicates reciprocating movement.
	Clockwise Rotation: Identifies the control or the indicator for clockwise rotary motion or for the adjustment or indication of rotation speed.
 XXXX min ^{-x}	Clockwise Rotation and speed: Indicates the use of clockwise rotary motion and recommended speed.
	Anti- clockwise rotation: Identifies the control or the indicator for anticlockwise rotary motion or for the adjustment or indication of rotation speed.
	Barbed Broach: Indicates the type of instrument.
	File type H: Indicates the type of instrument.

	File type K: Indicates the type of instrument.
	Rasp: Indicates the type of instrument.
	Reamer type K: Indicates the type of instrument.
	Paste carrier: Indicates the type of instrument.
	Double cutting edge (diamond): Indicates the type of instrument.
	Double helix file type H: Indicates the type of instrument.
	FG handle: Indicates the handle type.
	PM handle: Indicates the handle type.

	RA handle: Indicates the handle type.
	Double arrow: Indicates the (working) length of an instrument.
	Heat Carrier: Indicates to heat the plunger before filling material condensation.
	Optical fiber: Indicates a reference to the optical fiber applicator.
	Accessory: Indicates a part is considered an accessory to a product.
	IP Code: Indicates the degrees of protection provided by an enclosure against access to hazardous parts, ingress of solid foreign objects, ingress of water and to give additional information in connection with such protection.
	Bluetooth: Indicates that this product enables communication between Bluetooth-compatible devices.
	Information: Indicates where information is to be obtained.

	Information: Indicates additional information, explanation on operation and performance.
	Battery charger: Indicates to operate the device only with the provided battery charger.
	Foot pedal: Identifies the Foot pedal connection.
	Motor handpiece: Identifies the Motor handpiece connection.
	Lip clip: Identifies the Lip clip cable connection.
	File clip: Identifies the File clip cable connection.
	Information: Indicates a suggestion or advice.
	Limited rectilinear motion: Indicates limited rectilinear motion.

	<p>Information: Indicates that the reader should refer to another document.</p>
	<p>Rotary motion: Identifies the control or the indicator for rotary motion.</p>
	<p>Precautions: Indicates a measure taken in advance to prevent something dangerous, unpleasant, or inconvenient from happening.</p>

Manufacturer



VDW GmbH
 Bayerwaldstr. 15
 D-81737 München
 Phone +49 (0) 89 62734-0
 Fax +49 (0) 89 62734-304
 info@vdw-dental.com
 www.vdw-dental.com



www.vdw-dental.com/ifu