



Title D45 – Label Specification		Change Order # N/A
Author Crystel Pang	Document ID DOC-2187	Revision 3

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1. SCOPE

This document describes the Labeling Specification for the D45. This specification is based on the Labeling Requirements as captured in Greenlight Guru.

This document is applicable to the D45 (product label, product sticker) and to the label on the Packaging (packaging label, packaging sticker) of the D45. The Instructions for Use (IFU) is also part of the Labeling for the D45, but this is outside the scope of this document.

2. INTRODUCTION

Labeling is used to inform users about the medical device. The product label is the identification for a device that contains information for traceability. The D45 shall be identifiable with unique information that is located on the label. This way, there is complete traceability) throughout the product lifecycle.

Labeling can also be used to communicate important or safety related information. A product sticker can warn, inform, instruct or explain certain steps to a user. This helps the user to use the product correctly and avoid misuse or incorrect use.

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3. PRODUCT AND LABEL IDENTIFICATION

3.1. Unique Device Identification (UDI)

3.1.1. Background of UDI

The D45 uses a Unique Device Identification (UDI) code system to mark and identify products within the healthcare supply chain. The UDI codes are issued by the GS1.

3.1.2. UDI format

The Unique Device Identification (UDI) is constructed from (see also Figure 1):

- UDI – DI: Device Identifier (DI) – a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device; referred to a **Global Trade Item Number (GTIN)** by GS1. This DI is fixed to 14 numbers.
- UDI – PI: Product Identifier (PI) – a conditional, variable portion of a UDI code, which may include any of the identifiers specified below; each referred to as an **Application Identifier (AI)** by GS1;
 - Date the specific device was manufactured; fixed to 6 numeric characters, formatted as ‘YYMMDD’;
 - Serial number of the specific device; variable using up to 20 alphanumeric characters;

3.1.3. UDI requirements

- The UDI is provided on the product and/or package;
- The UDI is provided on the label in a plain-text version with each section of the UDI indicated by the identifying symbol; referred to as an Identifying Symbol by GS1;
 - (01) for the Device Identifier; GTIN (*see section 3.1.3.1*)
 - (11) for the Manufacturing Date (*see section 3.1.3.2*)
 - (21) for the Serial Number (*see section 3.1.3.3*)
- The plain text consists of legible characters that can be read by people (Human Readable Interpretation, HRI).
- The UDI is provided on the label in the form of an automatic identification and data capture (AIDC) technology; a Data Matrix. The size of the Data Matrix depends on the number of characters. The Data Matrix is generated according to ISO/IEC 16022:2006 / Cor 2:2011.

Example of UDI provided in plain-text:

(01)5102222233336(11)141231(10)A213B1(21)1234

Example of UDI provided in Data Matrix (and appears when scanned):

0151022222333361114123110A213B1211234

Unique Device Identifier (UDI)

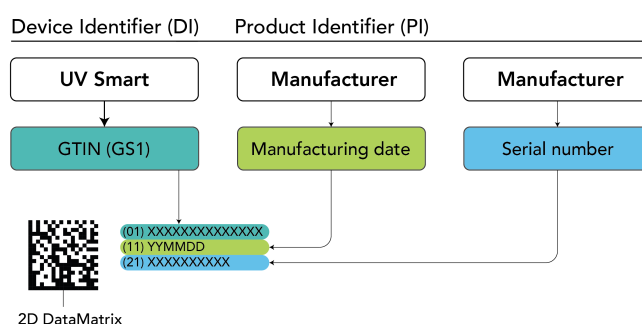


Figure 1: UDI – product traceability for D45.

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3.1.3.1. Identification of a trade item (GTIN): AI (01)

The GS1 Application Identifier (01) indicates that the GS1 Application Identifier data field contains a GTIN. The GTIN is built up from three parts; GS1 Company Prefix, Item reference and Check digit.

3.1.3.2. Production date: AI (11)

The GS1 Application Identifier (11) indicates that the GS1 Application Identifier data field contains a production date. The production date is the production or assembly date determined by the manufacturer. The date may refer to the trade item itself or to items contained. The structure is:

- Year: the tens and units of the year (e.g., 2003 = 03), which is mandatory.
- Month: the number of the month (e.g., January = 01), which is mandatory.
- Day: the number of the day of the relevant month (e.g., second day = 02).

3.1.3.3. Serial number: AI (21)

The GS1 Application Identifier (21) indicates that the GS1 Application Identifier data field contains a serial number. A serial number is assigned to an entity for its lifetime. When combined with a GTIN, a serial number uniquely identifies an individual item. The serial number field is alphanumeric and is assigned by its manufacturer.

3.2. Label Design Code

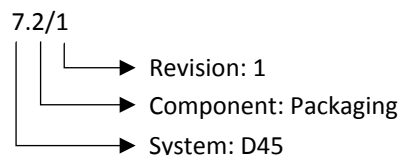
The D45 will have a label and a label reference: the label design code. This label design code links to the content of the label design and revision. The code consists of the following three characters:

A.B/C

Where:

- A = refers to the higher level product **system** within UV Smart.
The value for A being “7” refers to the D45.
- B = refers to the lower level **component** within that system. For the D45 the numbers are linked as follows:
“1” for the Product
“2” for the Packaging
“3” for the Product sticker
“4” for the Product sticker (EN/FR)
- C = refers to the **revision** of the label and is separated from the code with a “slash”.

Example of a label design code:



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3.3. Reference Number and Hardware Version Identification Number (HVIN)

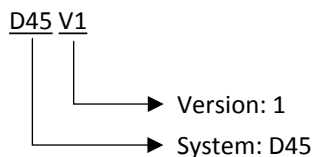
The D45 will have a reference number on the label which also indicates the Hardware Version Identification Number (HVIN). The Reference Number and HVIN refer to a specific product and version of UV Smart. The Reference Number and HVIN is also visible on the label of the packaging and has the following structure:

DSS VX

Where:

- DSS = refers to the higher level product **system** within UV Smart.
The value for SS being “45”, refers to the D45.
- VX = refers to the version of the product.
The value for X being “1”, refers to version 1 (V1) of the D45.

Example of a reference number and HVIN:



UV Smart is responsible for defining what a new version of the product is with Change Control.

Reference Number	Hardware Identification Number	GS1 GTIN
D45V1	D45V1	8719326634258

Table 1: Reference numbers D45.

3.4. Product Marketing Name (PMN)

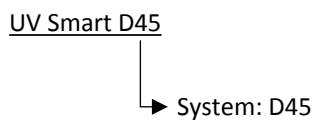
The D45 will have a Product Marketing Name on the Label. The name will also be visible on the label of the packaging and has the following structure:

UV Smart DSS

Where:

- DSS = refers to the higher level product **system** within UV Smart.
The value for SS being “45”, refers to the D45.

Example of a PMN:

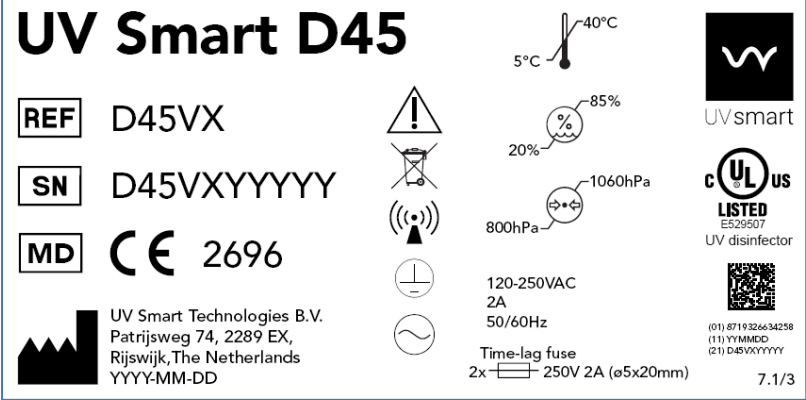
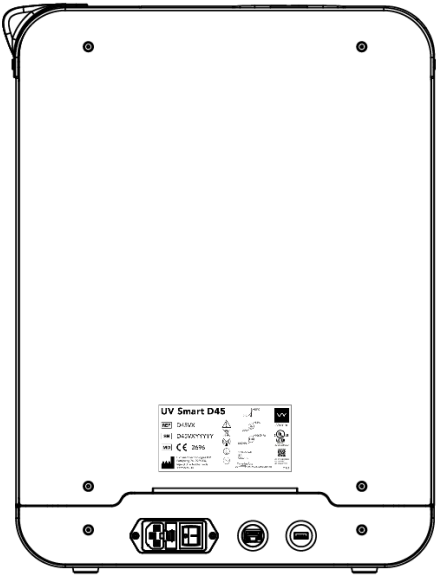


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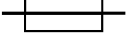
4. DEVICE LABELING

4.1. Product label

Table 2 below specifies the label that is attached to the D45 medical device.

Label visualization	 <i>Figure 2: Label visualization of the D45 product label (example).</i>
Label design code	7.1/3
Label position	 <i>Figure 3: Label location of the D45 product label (example).</i>
Label	Brady – MetaLabel™ ® Brady®
Compliance	UL approved, CSA accepted
Dimensions	2 inch x 4 inch (50,8 mm x 101,6 mm)
Color	Silver (Gloss)
Applicable symbols/information	Legal Manufacturer – symbol accompanied with address and manufacturing date  UV Smart Technologies B.V. Patrijsweg 74, 2289 EX, Rijswijk The Netherlands YYYY-MM-DD

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		Data Matrix containing the UDI, accompanied with the UDI text strings	 (example only)	
		To warn of a (potential) hot surface.		
		Waste Electrical and Electronic Equipment (WEEE) - symbol		
		Catalogue (reference) number - symbol with reference number text string	 D45VX	
		Serial number-symbol + serial number text string (see next section)	 D45VXDYYYY	
		Caution - symbol		
		Fuse		
		Ingress Protection classification	IP 21	
		Caution, non-ionizing electromagnetic radiation		
		UL certified as UV disinfectant (E529507)		
		Medical Device		
		CE marking + Notified Body number UDEM 2696		
		Temperature limit	Upper limit: 40 °C	
			Lower limit: 5 °C	
		Humidity limitation	Upper limit: 85 %	
			Lower limit: 20 %	
		Atmospheric pressure limitation	Upper limit: 1060 hPa	
Lower limit: 800 hPa				
Protective earth; protective ground (Class I equipment)				
Alternating current				
UDI	Device Identifier	GTIN number, 14 characters, see Appendix A. Accompanied by “(01)”. Where: - D45VX = D45V1 - XXXXXXXXXXXX = 8719326634258	D45VX (01) XXXXXXXXXXXXXXX	

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	Manufacturing Date	Fixed form “YYMMDD” (e.g. 190114 = 14 January 2019). Accompanied by “(11)”.	(11) YYMMDD
	Serial Number	Uniquely generated 10-character number, format: D45VXYYYYY Accompanied by “(21)”. Where: - D45 = fixed characters, referring to the project name “D45”. - VX = 2 digits referring to the version of the product. “V1” refers to version “1”. - YYYYY= 5 characters as a unique identifier, where “YYYYY” are 5 digits that will be unique for each device.	(21) D45VXYYYYY

Table 2: Product label of the D45.

4.2. Packaging label

Table 3 below specifies the label that is attached to the Packaging of the D45.

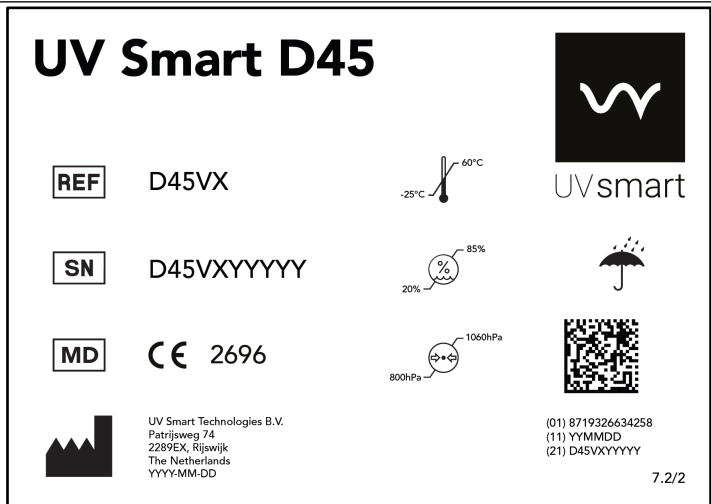
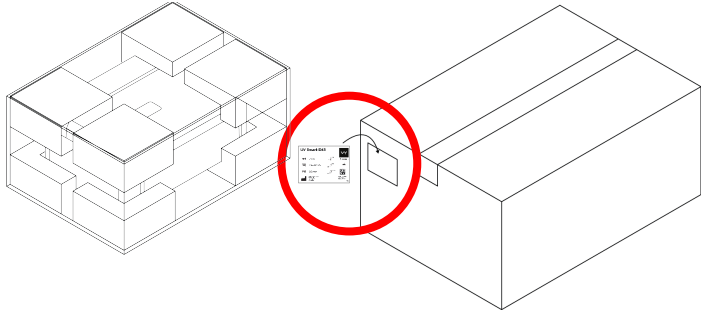
Label visualization	
Label design code	7.2/2
Label position	Visibly on the outside of the packaging box. 
Label	Printable label with self-adhesive layer.
Dimensions	A6 landscape 148 mm x 105 mm
Color	White

Figure 4: Label visualization of the D45 packaging label (example).

Figure 5: Label location of the D45 packaging label.

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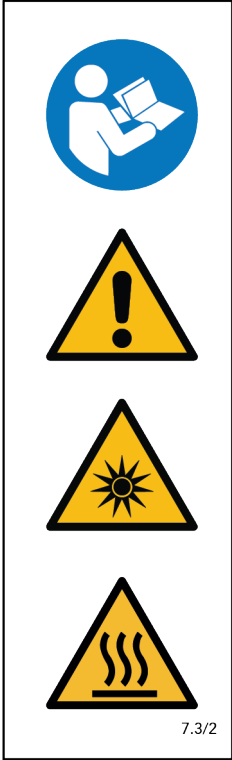
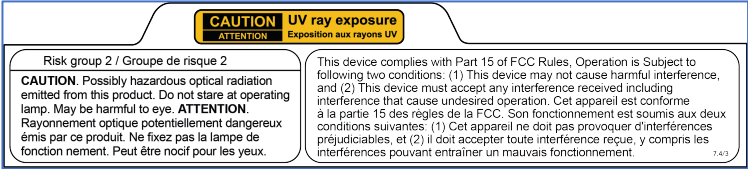
Applicable symbols/information		Legal Manufacturer – symbol accompanied with address and manufacturing date	 UV Smart Technologies B.V. Patrijsweg 74, 2289 EX, Rijswijk The Netherlands YYYY-MM-DD	
		Data Matrix containing the UDI, accompanied with the UDI text strings	 (example only)	
		Catalogue (reference) number - symbol with reference number text string	REF D45V1	
		Serial number-symbol + serial number text string (see next section)	SN D45V1YYYYYY	
		Medical Device	MD	
		CE marking + Notified Body number UDEM 2696		
		Keep dry		
		Temperature limit	Upper limit: 60°C	
			Lower limit: -25°C	
		Humidity limitation	Upper limit: 85%	
Lower limit: 20%				
Atmospheric pressure limitation	Upper limit: 1060 hPa			
	Lower limit: 800 hPa			
UDI		Similar as on Product label (see Chapter 4.1 Product label)		

Table 3: Packaging label of the D45.

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4.3. Product sticker

Table 4 below specifies the product sticker that is printed on the D45 to make the user more aware of the hazards that can occur when using the device incorrectly. The print also refers to the IFU booklet to ensure the users are aware of the training that is required to operate the D45.

Label visualization	 7.3/2 Figure 5: Label visualization of the D45 product sticker.  Figure 6: Label visualization of the D45 product sticker (EN/FR).
Label design code	7.3/2 and 7.4/3
Label position	Sticker on the disinfection chamber front panel.  Figure 7: Product sticker location of the D45.

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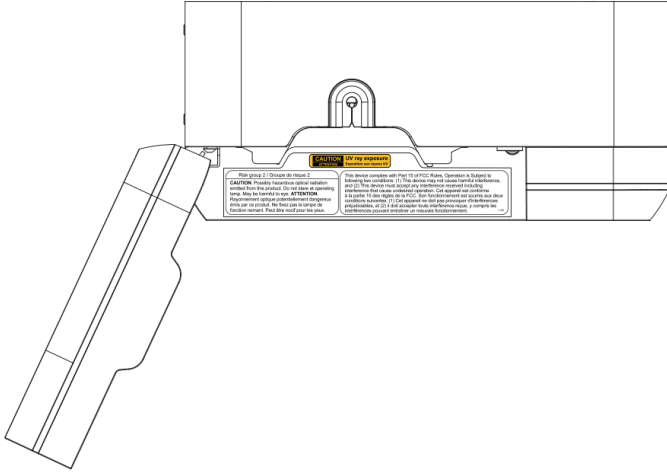
	Sticker on the top surface of the Plint.  <i>Figure 8: Product sticker (EN/FR) location of the D45 (top view).</i>	
Dimensions	Label 7.3/2 is 30 x 100 mm Label 7.4/3 is 225 x 50 mm	
Color	White, yellow, black, blue and transparent	
Applicable symbols/information	Refer to instruction manual/booklet – symbol	
	To indicate that caution is necessary when operating the device and to indicate that the current situation needs operator awareness	
	Optical radiation warning	
	Caution, hot surface	
	To indicate that caution is necessary when operating the device and to indicate that the current situation needs operator awareness	Risk group 2 / Groupe de risque 2
	To indicate that caution is necessary when operating the device and to indicate that the current situation needs operator awareness	CAUTION ATTENTION

Table 4: Product sticker of the D45.

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4.4. Packaging Sticker

Table 5 below specifies the packaging sticker that is attached to the D45 packaging to make people (transporter, distributor) more aware of the fragile content and to indicate the orientation of the Packaging Box. The Packaging Sticker is added on two sides of the box to increase visibility of the sticker.

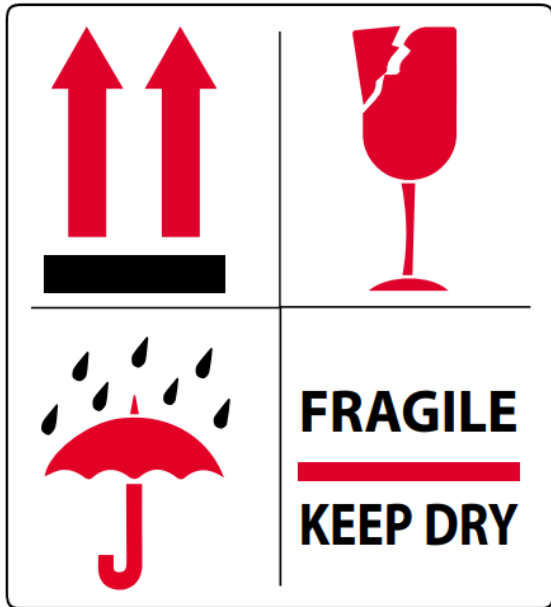
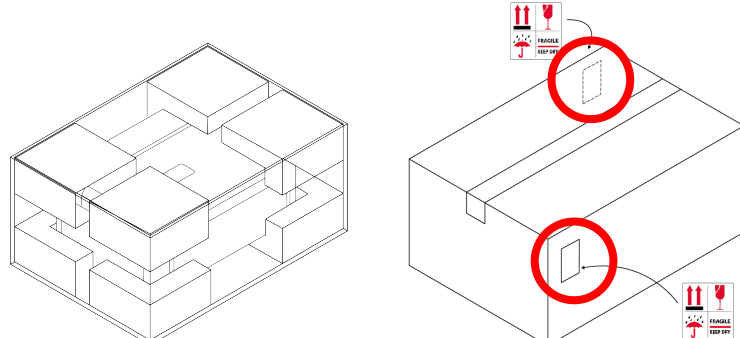
Label visualization		
Label position	Visibly on the outside of the packaging box. 	
Dimensions	110 x 100 mm	
Color	White, red and black	
	This way up; Indicates correct orientation of the package	
	Fragile; Contents of the package are fragile therefore should be handled with care.	
	Keep dry	

Table 5: Packaging sticker of the D45.

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5. LABEL REFERENCE

The labels for the D45 specified in this document are controlled in a separate document (DOC-ID) in Greenlight Guru. These documents specify the following label designs:

DOC-ID	Label title
DOC-2282	Product label
DOC-2286	Packaging label
DOC-2283	Product sticker
DOC-2285	Product sticker (EN/FR)
DOC-901	Packaging sticker

Table 6: DOC-ID's for D45 labels.

6. PART AND WIRE INDICATION

6.1. Protective Earth Ground Label

The aluminum parts of the D45 are protected with grounding wiring as specified in the applicable technical drawing. Each of these wires is indicated with a Protective Earth Ground Label (IEC 60417) on the aluminum parts. Refer Table 7 for an example. The size of these stickers is at least 15x15 millimeters.

6.2. Dangerous Voltage Label

The high voltage parts are indicated with a “high voltage” label. See Table 7 for the appearance of the label, which is at least 20 millimeters wide.

Label name	Label image	Label specification
Protective Earth Ground Label (IEC 60417 - 5019)		At least 15x15mm
Dangerous Voltage Label (IEC 60417 – 5036)		At least 20mm wide

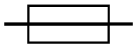
Table 7: Ground and Dangerous Voltage label specification.

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7. REVISION HISTORY

Revision	CO #	Description of change
0	N/A	Initial revision of label specification.
1	N/A	Addition of Hardware Version Identification Number (HVIN) and Product Market Name (PMN) specification in chapter 3. Update new revision number and figure of: - Product Sticker (DOC-2283), from rev1. to rev2; Correction revision number and figure of: - Product Sticker (EN/FR) (DOC-2285), from rev1 to rev3.
2	N/A	Update Product Label and Packaging Label (with CE-symbol) specifications. MD-symbol added to appendix.
3	N/A	Update Product Label with operational temperature (5-40 degrees Celsius). Removed UDI symbol as it is not applicable. Updated figure 6.

8. APPENDIX: SYMBOLS

#	Description	Symbol Ref. No.	Details
1	Manufacturer + full address	 5.1.1 ISO 15223-1	The manufacturer's name + full address shall be adjacent to the symbol.
2	GS1 Data Matrix	 (example)	Size and configuration based on the number of characters. Minimum size: 22 x 22 module. 0.25mm per module = 5,5 x 5,5 mm for Data Matrix
3	CE marking + Notified Body number (4 digits)	 XXXX	CE: at least 5 mm in height Where "xxxx" is to be replaced by the Notified Body number Notified Body number UDEM: 2696
4	Waste Electrical and Electronic Equipment (WEEE)	 Crossed-out wheeled bin	The symbol must be printed visibly, legibly and indelibly. Directive 2012-19-EU on WEEE
5	Catalogue number	 5.1.6 ISO 15223-1	The catalogue number shall be adjacent to the symbol.
6	Serial number	 5.1.7 ISO 15223-1	The serial number shall be adjacent to the symbol. The size of the symbol and Serial number must be readable for users.
7	Fuse		Indicates the required fuses in the D45
8	Input, alternating current	 5032 IEC 60417	Indicates that the equipment is suitable for alternating current only.

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9	Protective earth; protective ground (Class I equipment)	 5019 IEC 61140	Protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.
10	Ingress Protection classification	IP21 IEC 60529	The IP classification (Ingress Protection) rates the degrees of protection that electrical appliances have against the intrusion of water, solid objects and dust.
11	Temperature limit	 5.3.7 ISO 15223-1	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.
12	Humidity limitation	 5.3.8 ISO 15223-1	The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.
13	Atmospheric pressure limitation	 5.3.9 ISO 15223-1	The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.
14	Caution	 5.4.4 ISO 15223-1	Indicates the need for the user to consult the instructions for use for important information such as warnings and cautions.
15	Keep dry	 5.3.4 ISO 15223-1	Indicates a medical device that needs to be protected from moisture.
16	Refer to instruction manual / booklet	 ISO 7010 – M002	Indicates that the instruction manual / booklet must be read.
17	Non-ionizing electromagnetic radiation	 5140 IEC 60417	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
18	Dangerous voltage	 IEC 60417 - 5036	To indicate hazards arising from dangerous voltages.
19	Warning; Optical radiation	 ISO 7010 – W027	To warn of optical radiation

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20	Date of manufacture	 ISO 7010 – W027	To indicate the date on which a product was manufactured.
21	This way up	 ISO 7000 – 0623	Indicates correct orientation of the package.
22	Fragile	 ISO 7000 – 0621	Contents of the package are fragile therefore should be handled with care.
23	Caution, hot surface	 IEC 60417-5041 (2002-10)	To warn of a (potential) hot surface.
24	UL certified as UV disinfectant (E529507)		To indicate the device is UL certified
25	Medical device	 5.7.7 ISO 15223-1	Indicates the item is a medical device.

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Approved By:

Crystel Pang - Author

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