UV Smart MDR 2017/745 CE Classification 21-Nov-2024

To whom it concerns,

UV Smart Technologies B.V. is the legal manufacturer of the UV Smart D25, D45, and D60, which are medical devices specifically designed for the disinfection of medical equipment using UV-C light. These products are classified and certified under the applicable regulations to ensure compliance, safety and market access.

In the European Union, these devices are governed by the **Medical Device Regulation (MDR) (EU) 2017/745**, which has replaced the former **Medical Device Directive (MDD)**. The MDR came into effect on **May 28, 2021**, and legal manufacturers have been granted a transitional grace period to update their technical files from the MDD to the MDR until **December 31, 2028**, to align with the new regulatory requirements.

Manufacturers with MDD certified products must have transferred their technical file **before 26 September 2024** to an appropriate Notified Body to maintain compliance during the transitional period. Failure to meet this deadline invalidates the MDD certificate. In such cases, a **Confirmation Letter** from the Notified Body is required to verify the validity of the MDD CE certificate and allow continued market release of these products during the transition.

The UV Smart D25, D45, and D60 are **Class IIa CE certified medical devices** in accordance with **MDR Section 7.3, Rule 16**. This classification has been thoroughly reviewed and confirmed by UDEM Adriatic d.o.o. (Notified Body Number 2696) and validated by **The European Commission (Annex I).** This ensures UV Smart devices meet MDR compliance standards for the long term.

7.3. Rule 16

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb.

All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as class IIb.

This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

Figure 1 - Rule 16 as defined in the Medical Device Regulation (EU) 2017/745

Rule 16 of the MDR 2017/745 specifies requirements for disinfection-related medical devices. The term "solutions" within this rule refers to **chemical disinfection solutions**. The UV Smart D25, D45, and D60 do not fall under this category, nor are they classified as washer-disinfectors. As such, these devices appropriately fall under the **Class IIa classification**.

The MDR is a legally binding regulation applied across all EU Member States. It must be implemented in its entirety and is not open to subjective interpretation. UV Smart Technologies B.V. strictly adheres to these requirements, ensuring full regulatory compliance.

For further clarification or documentation regarding this declaration, please do not hesitate to contact us.

Sincerely,

Thijs Kea
Co-Founder / PRRC

UV Smart Technologies B.V.
Patrijsweg 74
2289 EX, Rijswijk

+31 (0)85 060 98 00
info@uvsmart.nl
uvsmart.nl

ANNEX I

Deniz Duman

From: Europe Direct Contact Centre <EuropeDirectContactCentre@edcc.ec.europa.eu>
Sent: Monday, 29 July 2024 11:45
To: Deniz Duman
Subject: Your Europe Direct reply no #4253891

U ontvangt niet vaak e-mail van europedirectcontactcentre@edcc.ec.europa.eu. Meer informatie over waarom dit belangrijk is

Dear Mr Duman,

Thank you for your message which has been forwarded to us by the Eur-Lex Helpdesk.

We have consulted the Directorate General for Health and Food Safety (DG SANTE). Please find below the answer to your question.

"Following you can find some clarifications but consider that the European Commission is not responsible for disputes on classification of medical devices. In accordance with Article 51(2) of Regulation (EU) 2017/745, any dispute between the manufacturer and the notified body, arising from the application of Annex VIII of the Regulation, shall be referred for a decision to the competent authority of the Member State in which the manufacturer has its registered place of business. In case of interest, the contacts of the competent authorities on medical devices are available on the relevant Commission website.

The second paragraph of classification Rule 16 (see Section 7.3 of Annex VIII to Regulation (EU) 2017/745 on medical devices), establishes that all devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa. By way of derogation from this general rule, disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, are classified as class IIb.

The intended purpose of a washer-disinfector affects its classification. In fact, a washer-disinfector is classified as class IIb if it is intended to wash and disinfect invasive devices, as the end point of its processing. The term "disinfecting solutions" used in the second paragraph of Rule 16, should be considered not referring to a piece of equipment, rather to a homogeneous mixture of one or more solutes dissolved in a solvent.

The document MDCG 2021-24 "Guidance on classification of medical devices" contains additional useful information and clarifications on classification of medical devices. On page 49, you can find information on Rule 16."

We hope you find this information useful. Please contact us again if you have other questions about the European Union, its activities or its institutions.

Created on: 2024-07-04 09:40:24

UV Smart Technologies B.V.
Patrijsweg 74
2289 EX, Rijswijk

+31 (0)85 060 98 00
info@uvsmart.nl
uvsmart.nl