

The CE certificate of the 45-liter Class IIb medical autoclave (model STE-45-T) from Icanclave has been extended in accordance with Regulation (EU) 2023/607 due to transitional provisions outlined for medical devices certified under Directive 93/42/EEC. Key reasons include:

1. **Extension of Validity for Class IIb Devices:** According to Article 120(3a)(b) of the regulation, Class IIb devices other than implantable devices have their certificates extended until **31 December 2028** provided specific conditions are met.

procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.’;

(b) paragraph 3 is replaced by the following:

‘3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

2. **Prevention of Device Shortages:** The extension is implemented to avoid disruptions in the availability of medical devices in the European Union, ensuring uninterrupted healthcare services.
3. **Compliance Requirements:** The device must:
  - Continue to comply with Directive 93/42/EEC.
  - Not undergo significant changes in design or intended purpose.
  - Maintain safety standards without presenting unacceptable risks.
4. **Transition to Regulation (EU) 2017/745:** The extension allows manufacturers sufficient time to align with the updated requirements under Regulation (EU) 2017/745 by 2024, including the implementation of a compliant quality management system and application for conformity assessment.

This regulatory adjustment acknowledges the limitations of notified body capacities and the challenges faced by manufacturers in transitioning to the newer framework while ensuring the continued safe use of medical devices.