
Notification of Product Changes in Compliance with MDR
(Effective July 1, 2026)

NO: ICXS-2026052501 A/0

Date: May 25, 2026

Dear Valued Customer,

In accordance with the requirements of the EU Medical Device Regulation (MDR), we would like to inform you of a design change related to the following sterilizer models:

ICANCLAVE STE-29-T

ICANCLAVE STE-45-T

CLAVEMED STE-29-T PRO

CLAVEMED STE-45-T PRO

CLAVEMED STE-50-T PRO

Description of the Change

The current design of the door microswitch actuator (trigger rod) is externally exposed. To further improve operational safety and reduce the possibility of accidental contact by users, the following design modifications will be implemented:

The position of the door microswitch actuator will be relocated inside the door panel, making it inaccessible from the outside.

The door cover push rod will be extended accordingly to ensure proper operation of the door system.

Purpose of the Change

This modification is intended to prevent accidental triggering of the door microswitch, which could otherwise cause unintended door motor movement.

Implementation Date

The updated design will be implemented for production starting from:

July 1, 2026

Please note that this change does not affect the intended use, sterilization performance, or essential safety and performance of the device.

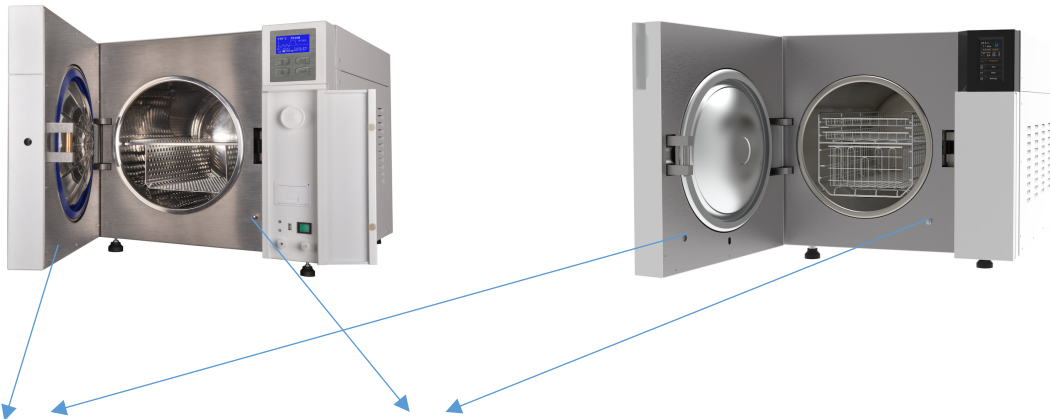
Should you have any questions regarding this notification, please feel free to contact us.

Thank you for your continued trust and support.

Best regards,

Kind regards,
Icanclave Team
Quality & Regulatory Affairs

Best Regards,
Ningbo Ican Machines Co.,Ltd



New xtended Push rod	New position of Door microswitch actuator	Old position of door microswitch actuator
	