

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1464-2022

Replacing YY/T 1464-2016

**Sterilization of healthcare products - Low temperature steam
formaldehyde - Requirements for the development, validation
and routine control of medical device sterilization processes**

(English Translation)

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What this standard covers

This standard specifies the requirements for the development, validation and routine control of the low temperature steam formaldehyde sterilization process for medical devices. This standard applies to the sterilization process using mixed low-temperature steam formaldehyde as a sterilization factor under negative pressure conditions. This standard does not apply to the requirements for the development, validation and routine control of spongiform encephalopathy (such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease) pathogen inactivation process.

Document data

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