



中华人民共和国国家标准
NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 18279.1-2015

**Sterilization of health care productsⁱ Ethylene
oxideⁱ Part 1: Requirements for
development, validation and routine control of a
sterilization process for medical devices**

Issued Date:

Implemented Date:

Issued by:

The General Administration of Quality Supervision, Inspection and Quarantine of
the People's Republic of China , The Standardization Administration of the
People's Republic of China

Foreword

The English version hereof has been translated directly from the openly-published Chinese standard 'GB 18279.1-2015 Sterilization of health care products—Ethylene oxide—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices'.

In the event of any discrepancy in the process of implementation, the Chinese version 'GB 18279.1-2015 Sterilization of health care products—Ethylene oxide—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices' standard shall prevail.

This is a preview version of GB 18279.1-2015 standard ;
The GB 18279.1-2015 standard official version needs to be
purchased .

What is GB 18279.1-2015 standard?

GB 18279.1-2015 standard is the China national standard for "Sterilization of health care products²Ethylene oxide²Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices" ; GB standard also called as Guo Biao Standards, China GB standards are classified as two stages, Mandatory or Recommended. Mandatory standards have the force of law as do other technical regulations in China. They are enforced by laws and administrative regulations and concern the protection of human health, personal property and safety. All standards that fall outside of these characteristics are considered Recommended standards. China GB standards can be identified as Mandatory or Recommended by their prefix code, Prefix code GB are Mandatory standards, GB/T are Recommended standards (Quasi-Mandatory standards) ;

Why do I need to be compliance with GB 18279.1-2015 Standard?

In China, All products or services must be complied with GB standards, no matter domestic or imported products, Any products being sold in China are required to be tested in order to ensure their compliance with GB standards; If you want to export products or services to huge Chinese market, need to understand and be aware of the complexities and necessary requirements under the vast range of GB standards, need to ensure they are meet the requirements of china national GB standards; The outcome of failing to comply with GB standards can include the rejection of products during importation as well as products being seized from stores, resulting in a significant impact on retailers and manufacturers in terms of reputation and cost.



GB Standards Free Search Service

More than 100,000 China National GB Standards, Industry standards & Regulations database for free search. You can easily lookup the China GB standards for any products and services by Multiple query methods, keyword fuzzy search, China GB standards code exact query, etc.



GB Standards English Translation Service

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GB Standard Laboratory Testing Service

In China, all products being imported in China are required to be tested in order to ensure their compliance with GB standards; We cooperate with many China government authorized test institute, Can provide all GB standards test, These test reports are recognized by all Chinese supervision, Such as CFDA, CNCA, MOA, AQSIQ, CIQ, Customs, etc.



GB Standard Compliance Analysis Service

We can help ensure your product meet quality, safety and compliance to Chinese GB standards and other regulation requirements. We offer you expert knowledge in product compliance and conformance to GB standards specifications, providing a range of services to support you in selling your products in China.