

ICS 11.040
CCS C 30

SN

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

SN/T 3062.1-2011

**Packing materials for terminally sterilized medical devices for
import. Part 1: Validation requirements for forming, sealing and
assembly processes**

进口医疗器械灭菌包装 第1部分：成形 密封和装配过程的确认要求
(English Translation)

Issued on: September 30, 2011

Implemented on: April 1, 2012

Issued by: General Administration of Customs

Table of Contents

What this standard covers	1
Document data	2
Standards quoted by this document	3

What this standard covers

This standard specifies the imports of medical equipment sterilization packaging process development and validation requirements. These processes include preformed sterile barrier systems, barrier systems and packaging systems forming, sealing and assembly. This standard applies to imports of medical equipment sterilization preformed sterile barrier systems, barrier systems and packaging systems for forming, sealing and assembly confirmation. This section does not include packaging of sterile medical device manufacturing requirements.

Document data

International classification (ICS): 11.040.

Chinese classification (CCS): C30.

Estimated length of the Chinese original: 11,128 words.

Adopted international standard: ISO 11607-2-2006, IDT.

Standards quoted by this document

ISO 11607-1-2006