

TECHNICAL DATA SHEET



Product Name and Code:

Rapid Challenge Pack – LPCD25

Product Description:

The LISTER Rapid Challenge Pack is specifically designed to qualify and monitor vacuum-assisted steam sterilization processes at 132°C to 135°C in healthcare facilities. The challenge pack consists of multiple layers of medical index cards, some of which are die-cut to contain the biological indicators. The stacked cards are wrapped with a sterilization wrap. Each challenge pack has a process indicator on the pack label that changes from yellow to grey or black when exposed to steam. This convenient disposable challenge pack presents a challenge to the sterilization process equivalent to the user-assembled biological indicator (BI) challenge test pack (towel PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI). The challenge pack is a single use device.

Each challenge pack contains a LISTER Rapid Readout Biological Indicator(LBS180), and a record keeping sheet.



Indications for use:

Use the LISTER Rapid in conjunction with the LISTER Auto-reader BIOPT2, or the LISTER Mini Auto-reader BIOPT1 to qualify or monitor 132°C to 135°C vacuum-assisted steam sterilization cycles.

Performance characteristics:

BI	Please refer to the TDS of the corresponding model product for details.
PCD	Provide a challenge to the sterilization process equivalent to the user-assembled biological indicator (BI) challenge test pack (towel PCD) recommended by the Association for the Advancement of Medical Instrumentation (AAMI).

Technical information:

Weight of PCD	199-201g / bag
Period of validity	24 months
Dimensions	15.0 cm×11.2 cm

Compliance:

Manufactured by: LISTER BIOMEDICAL CO.,LTD.
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ISO 11138-1:2017 Sterilization of health care products-Biological indicators-Part 1: General requirements.
ISO 11138-3:2017 Sterilization of healthcare products-Biological indicators-Part 3 Biological indicators for moist heat sterilization processes.
ISO 11138-8:2021 Sterilization of healthcare products-Biological indicators-Part 8 Method for validation of a reduced incubation time for a biological indicator.
ISO 11140-1:2014 Sterilization of health care products-Chemical indicators-Part 1: General requirements.

Package:

50PCS/CTN

Version: 20240924