

MEMORANDUM

From: Alain Tremblay, Regulatory Affairs, Patterson Dental Canada
Date: 2017-02-01
RE: Patterson Pouch Plus ISO 11140-1 Class 4 Compliance

The purpose of this memorandum is to confirm compliance of the Patterson Pouch Plus autoclave sterilization pouches to ISO 11140-1 Class 4.

The Patterson Pouch Plus self-sealing sterilization pouches with multi-parameter internal and external process indicators are designed for use in steam and ethylene oxide sterilization systems.

ISO 11140-1 Class 4 steam chemical indicators are defined as a multi-variable indicator:

“A multi-variable indicator shall be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variable.”

The indicators on Patterson Pouch Plus react to multi-parameters defined as concurrent exposure to temperature, time, sterilant presence / concentration, and relative humidity.

STEAM

The indicator turns from pink to cocoa when processed as per values on the product packaging.

EO

The indicator turns from blue to golden brown when processed as per values on the product packaging.

The FDA does not recognize Class 3, 4 or 5 indicators as defined in ISO 11140-1:2005. This product is sold in both the USA and Canada. Therefore, to avoid confusion, the product packaging does not state compliance to the class 4 specification. The indicators on the pouches also meet ISO 11140-1 class 1 requirements.

This memorandum applies to the following product numbers:

084-2575 084-2625
084-2583 084-2633
084-2591 043-7558
084-2609 043-7574
084-2617 043-7541