

Friday, June 5, 2026

Dear Customer,

Oliver™ Healthcare Packaging facilities in Venray, Grand Rapids, Feasterville, New Britain, Hamilton, Suzhou, and Johor confirm that the standard packaging materials they supply to the medical device industry comply with ISO 11607:2019 as follows:

Oliver continues to conform to the applicable sections of ISO 11607-1, as communicated in advance and mutually agreed, for each specific application. This includes the manufacturer responsibilities in Part 1, specifically Section 4.1, "Quality Systems," Section 4.3, "Sampling," Section 5, "Materials and preformed sterile barrier systems," and Section 11, "Information to be provided."

Oliver supports customers with ISO 11607-2 compliance by performing process validations for preformed sterile barrier pouches and lid stock. These validations may be completed using the customer's protocols or Oliver's internal protocols. Oliver has performed installation qualification, operational qualification, and performance qualification on the equipment used to produce these pouches and lids. All testing is conducted within our ISO 13485:2016-certified Quality Management System. Customers remain responsible for the correct application of the packaging and, therefore, the final quality of the packaging design and system. Oliver remains responsible for the quality of the packaging materials as supplied, as documented in the certificate of analysis or certificate of conformance provided at the time of sale.

It is also important to note that ISO 11607:2019 AMD 2023 is harmonized with the applicable European Medical Device Regulation (MDR) 2017/745 for terminally sterilized medical packaging.

The 2019 and 2020 editions of ISO 11607 are identical, as stated in the standard: "The text of ISO 11607-1:2019/A1:2023 has been approved by CEN as EN ISO 11607-1:2020/A1:2023 without any modification." ISO 11607-2:2019/A1:2023 also incorporates risk management, which Oliver addresses as part of its ISO 13485 Quality Management System.

Please feel free to contact your sales representative should you require additional assistance.

Sincerely,

A handwritten signature in blue ink that reads 'Geoff Pavey'.

Geoff Pavey
Technical Fellow
Oliver™ Healthcare Packaging