



Transition of our quality management from ISO 9001 certification to ISO 13485

Dear valued customer,

With a clear vision of responsible quality management and with a touch of pride, we look back on the past nine years. During this time, we first successfully implemented our certification according to the ISO 13485 standard and then continuously improved it to the highest possible level. Consequently, today we meet the highest requirements for a quality management system for medical devices.

The ISO 13485 standard is similar in structure and purpose to the well-known ISO 9001 standard, according to which we are also certified until today. However, ISO 13485 goes significantly beyond ISO 9001 with its specific requirements and specifications for medical device manufacturers. With the EU Medical Device Regulation (MDR) coming into force in 2021, we believe that ISO 9001 certification no longer meets the current requirements of our market and is not an adequate substitute for ISO 13485 certification.

For this reason, we will phase out the ISO 9001 certification for our VP Medical Packaging and Stericlin® business units in August. At the same time, our ISO 13485 certification will take full effect. Going forward, we will focus entirely on maintaining and further developing our quality management system in accordance with ISO 13485 – in the spirit of responsible and future-proof action as a manufacturer of medical devices and packaging for medical devices.

Our current ISO 13485 certificate is available at any time in the download area of our website.

Feuchtwangen, July 2025

Yours faithfully

Thomas Lechner
Head of Management Systems VP Group