TECHPAD

SMARTeZ™ Pump • eZS™ Pump

Non-electrically Driven Portable Infusion Pumps

Natural Rubber Latex (NRL) Sensitivity

The FDA has issued a Latex Labeling requirement, 21 CFR 801.437 that states: "A labeling statement is required for devices that contain natural rubber when the rubber contacts humans".[1] The European Commission has a similar requirement on NRL.[2]

"SMARTeZ™ Pump and eZS™ Pump are totally free from Natural Rubber Latex nor Rubber Products"

Latex sensitivity is an issue that has been built into the design of SMARTeZ™ Pump and eZS™ Pump. While 21 CFR 801.437 states that no rubber should have "human contact" etc., we recognize that the contact may take the form of precipitation of moisture when the device is taken out from its refrigerated state. The SMARTeZ™ Pump has multi-layered membrane to provide the specific requirements of drug compatibility, pump performance and patient-user protection. These are not made from natural rubber latex but with synthetic thermoplastic elastomers. The outer cover generally provides a barrier to patient contact with the drug reservoir which would be critical if there are latex or rubber products used in the outer most membrane layer. With the SMARTeZ™ Pump, patients are totally assured of the absence of latex sensitivity risks because there is no latex material present.

Independent OECD laboratory testing[3], which include biocompatibility testing and chemical characterization for leachables/extractables have been conducted on SMARTeZ™ Pump and eZS™ Pump fluid pathway materials to measure the potential toxic substance extracted. ISO 10993 global standard methods were used.

Based on the global testing methods that are also recognized by (US) FDA, no harmful substances were detected for all test methods for the fluid pathway materials of the final, finished SMARTeZ™ Pump and eZS™ Pump.

Not only none of the system components are made from natural rubber latex, the manufacturing processes do not use natural rubber latex on any device contacting surfaces.

Conclusion: There is no natural rubber latex in the SMARTeZ™ Pump and eZS™ Pump. In addition, laboratory testing could not detect any extractable proteins from the pump fluid pathways that might migrate into the device during the process of manufacturing.

Please contact our representatives in the US at 800-969-6331 or in Europe at +49-6894-58120 if you have any questions regarding this information. Alternatively contact us directly at: +66-38-010-807 or http://www.epic-med.com

[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=801.437
[2] http://ec.europa.eu/health/medical-devices/files/meddev/2_5_9rev_latex_en.pdf
[3] TÜV SÜD PSB Pte. Ltd. (http://www.tuv-sud-psb.sg/)