Declaration of conformity



4371

Polystyrene, sterile, individually sealed

Lot Number: all lots

Our commitment to customers.

INTEGRA Biosciences polymer products are using precise and consistent manufacturing techniques that ensure quality and excellent performance. We strive to exceed our customers' expectations and encourage continuous feedback. The reservoirs are manufactured in accordance to ISO 9001.

Our product lots are traceable down to the corresponding raw materials used and date produced.

Our manufacturing process incorporates consistent and continuous inspection throughout all phases of the manufacturing process. The reservoirs produced under these strict conditions are contaminant free and consistent from lot-to-lot.

High Sensitivity Endotoxin Testing:

For products used in endotoxin testing we have performed additional testing for the presence of endotoxins.

Our Swiss reference lab, accredited to ISO 17025, performed additional lot-specific Limulus amoebocyte lysate (LAL) test using the turbidimetric test procedure conforming to EP 2.6.14 / USP <85>. The cut-off level for endotoxin acceptance is set at at: 0.005 EU/ml.

Urs Hartmann

CEO

INTEGRA Biosciences AG

Dr. Daniel Bächi Head of Corporate Quality INTEGRA Biosciences AG



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