

Design Verification Summary Report

MiniMed Mio with SC1

Design Verification Status

The infusion set MiniMed Mio with SC1 are marked with 3 year shelf life. Design Verification status inclusive 3 years shelf life tests are listed below in table 1.

Test	Criteria Description	Results
Flow test	Accept criteria: Min. 40 ml/min at 1.0 bar	Passed
Leak test	Accept criteria: No leak under water at 1,4 bar for 30 sec.	Passed
Dynamic pull test Cannula house house / Connector	Accept criteria: Minimum 15 N	Passed
Dynamic pull test Cannula house / Adhesive tape	Accept criteria: Minimum 15 N	Passed
Dynamic pull test Tubing / SC1	Accept criteria: Minimum 15 N	Passed
Dynamic pull test Tubing / Connector	Accept criteria: Minimum 15 N	Passed
Dynamic pull test Soft Cannula	Accept criteria: Minimum 3 N	Passed
Dynamic pull test Spring / Introducer Needle	Accept criteria: Minimum 10 N	Passed
Bending test Tubing / SC1	Accept criteria: No leak and no breaks at tubing after 3000 bending	Passed
Dynamic loading force of spring	Accept criteria: Minimum 15,5 N – Maximum 25 N	Passed
Burst test – Sertter (Packaging test)	Accept criteria: Minimum 244 cm H ₂ O	Passed
Transportation test	According to ASTM D4169-16, distribution cycle 13	Passed
Biocompatibility test	According to DS/EN ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process	Passed
Usability test	According to DS/EN 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices	Passed

Table 1: Design Verification status inclusive 3 year shelf life tests



All samples submitted for testing passed their respective tests as defined per Design Verification Test Program. Results have been documented in approved Unomedical reports.

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