Design Verification Summary Report

Quick Set with SC1

Design Verification Status

The infusion set Quick Set 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 seconds	Passed
Dynamic pull soft cannula	Accept criteria: > 3 N	Passed
Dynamic pull test Introducer Needle / Introducer Needle Hub	Accept criteria: > 10 N	Passed
Static pull test Base / Connector	Accept criteria: 1,5 kg for 15 second	Passed
Dynamic pull test Base / Adhesive tape	Accept criteria: > 22,5 N	Passed
Dynamic pull test Tubing / Hub (Luer and SC1)	Accept criteria: > 22,5 N	Passed
Dynamic pull test Tubing / Connector	Accept criteria: > 22,5 N	Passed
Bending test Tubing / Hub (Luer and SC1)	Accept criteria: No leaks and no breaks at Tubing after 3000 bendings	Passed
Peel strength of blister package (Packaging test)	Accept criteria: Minimum 1,2 N peel strength per 15 mm seal	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

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Sterility test	According to DS/EN ISO 10993-7:2008, Clause 4.3.2 Note from the French Authorities on Referral to the Standardization Committee (Regulation (EU) No 1025/2012) California Proposition 65, Art. 7: NO significant Risk Levels - § 25705: Specific regulatory levels posing NO significant Risk DS/EN ISO 556-1:2001, Clause 4.1 DS/EN ISO 556-1:2001, Clause 4.1	Passed (D019-001003)

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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06-MAR-2020

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