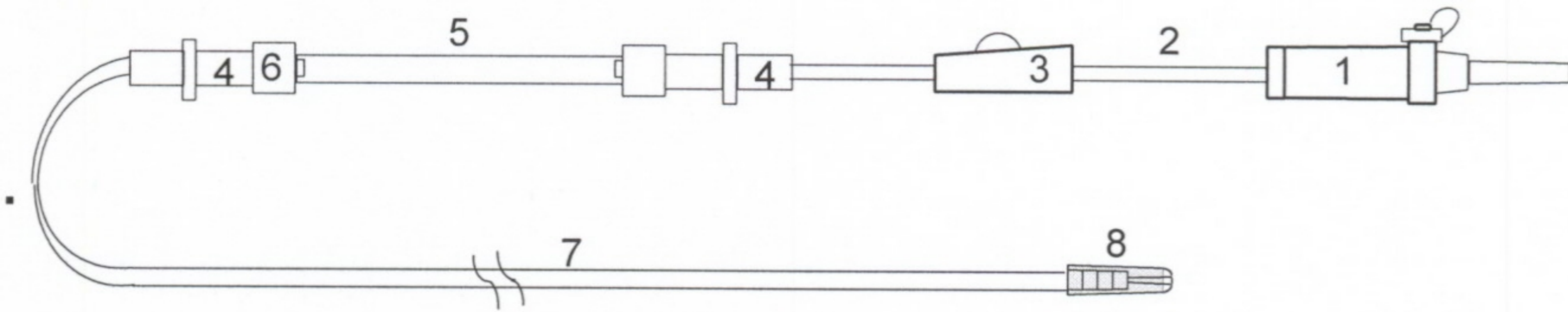


Irrigation tubing

REF 436360

WH.36 3/6



Material specification

Part-no.	Description	REF-no.	Material	Test of biocompatibility
1	Dripchamber	Code: pf0365 LN 125	Lustran (ABS)	Medicale grade FDA; ISO 10993
2	Tube	LN 223h	PVC 3	Medicale grade Fullfilled: Test for cytotoxicity ( ISO10993) Intracutaneous Injection test Acute Systemic Injection test Maximization test Implantation test (ISO 10993) Haemocompatibility ( ISO 10993 ) Haemolysis test( ISO 10993 ) Reverse Mutations in Salmonella Typhimurium
3	Roller clamp	Code: pf 0306/ pf0377 LN 124a	Polystyre ne 473 D	Medicale grade FDA 21 CFR 177.1640
4	Pump fixation	LN 128	PVC3	Medicale grade ISO 10993-1 USP class VI Fullfilled: Test for cytotoxicity :in vitro method Intracutaneous Injection test in the Rabbit Acute Systemic Injection test in the Mouse Hemolysis Test Implantation test in the Rabbit Haemocompatibility Partial Thromboplastin Haemolysis test( ISO 10993 ) Haemolysis test( ISO 10993 ) Reverse Mutations in Salmonella Typhimurium
5	Pump tube	LN 311	Silikon	Medicale grade Fullfilled: FDA 177 2600 USP Class VI BGW / BGA XV Pharmacopée Europeene 3. Edition Acute System Toxicity (USP) Intracutaneous Toxicity (USP) Implantation Test (USP)
6	Binding ring	LN 128f	PVC 3	Medicale grade Fullfilled: Test for cytotoxicity ( ISO10993) Intracutaneous Injection test Acute Systemic Injection test Maximization test Implantation test (ISO 10993) Haemocompatibility ( ISO 10993 ) Haemolysis test( ISO 10993 ) Reverse Mutations in Salmonella Typhimurium

Medical Disposables

# ASSA med

Part-no.	Description	REF-no.	Material	Supplier	Test of biocompatibility
7	Tube	LN 159	PVC 1	Modenplast	Medical grade Fullfilled: Test for cytotoxicity ( ISO10993) Intracutaneous Injection test Acute Systemic Injection test Maximization test Implantationstest (ISO 10993) Haemocompatibility ( ISO 10993 ) Haemolysis test( ISO 10993 ) Reverse Mutation in Salmonella Typhimurium Pirogenicity Test
8	Connector	Cod: SSV LN 108	PVC 5	Modenplast	Medical grade: Fullfilled: Test for cytotoxicity ( ISO10993) Intracutaneous Injection test Acute Systemic Injection test Maximization test Implantationstest (ISO 10993) Haemocompatibility ( ISO 10993 ) Haemolysis test( ISO 10993 ) Reverse Mutation in Salmonella Typhimurium