

4. COMPLIANCE

REFERENCE	TITLE	CONCLUSION
(EU) No 10/2011	Plastic materials and articles intended to come into contact with food	MEETS CRITERIA
(EU) No 1935/2004	Simulant B (3% Acetic acid aqueous solution) and Simulant D1 (50% ethanol)	MEETS CRITERIA
FDA 21 CFR 177.2600	Rubber articles intended for repeated use, FDA ITEM 177.2600 (e)	MEETS CRITERIA
BfR recommendation XV	Recommendations on the health assessment of plastics and other high polymers	MEETS CRITERIA
United States Pharmacopoeia <88>	Biological reactivity tests, <i>IN VIVO Class VI - 121° C</i>	MEETS CRITERIA
ISO 10993-4	Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood	MEETS CRITERIA
ISO 10993-5 & USP <87>	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	MEETS CRITERIA
ISO 10993-6	Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation	MEETS CRITERIA
ISO 10993-10	Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	MEETS CRITERIA
3A 18-03	Sanitary Standard Procedure Nº 18-03 Class I	MEETS CRITERIA
European Pharmacopoeia 3.1.9.	Silicone elastomer for closures and tubing	MEETS CRITERIA
Extractables and Leachables study available for 70ShA silicone	Extraction experiment in organic solvent Extraction experiment in polar organic-aqueous solvent system Extraction experiment in aqueous solvent, alkaline conditions Extraction experiment in aqueous solvent, acidic conditions	MEETS CRITERIA MEETS CRITERIA MEETS CRITERIA MEETS CRITERIA

Table 3 Compliance and results of tests done