

1. ISO Specified class 10000 clean room which also a USFDA and CDSCO Approved Facility his
2. LSR MENSTRUAL CUP
3. Biocompatibility studies From CDSCO approved NABL Lab

VALIDATION STUDIES	DESCRIPTION
ISO 10993-3	GENOTOXICITY
ISO 10993-4	HEMOLYSIS
ISO 10993-5	IN VITRO CYTOTOXICITY
ISO 10993-10	SKIN SENSITIZATION
ISO 10993-23	VAGINAL IRRITATION

Medical Grade Silicon with following

Validation

VALIDATION STUDIES
FDA 21CFR 177.2600
ROHSCOMPLIANT
TSE-BSE FREE
USP VI
BPA FREE
PHTHALATE FREE

Required product specification

1. Pink colour	DESCRIPTION	VALIDATION STUDY
2. Round paper container		
3. All certificate printed on in Box		
	GENOTOXICITY	ISO 10882-2
	HEMOTOXIS	ISO 10882-1
	IN VITRO CYTOTOXICITY	ISO 10882-2
	SKIN SENSITISATION	ISO 10882-10
	OCULAR IRRITATION	ISO 10882-59

Medical Grade Silicon and following

Applications

VALIDATION STUDY
ISO 10882-2500
ROHS COMPLIANT
IEC-826 FREE
UL60481
IP67 FREE
PHthalate FREE