I. PURPOSE:

This Work instruction provide the parameter which are must applied SPC control for Kodama catheter product.

II. APPLICATION:

This Work instruction concerns PRD, QAS Department

III. REFERENCE DOCUMENTS:

4-Pr-008:	SPC procedure
4-OP-345:	Kodama catheter
4-OP-614:	Hydrophilic coating

IV. TERM DEFINITION

V. FLOWCHART

Checked by : Dao Ngoc Trung	Approved by: Nguyễn Hữu Phượng Vân
Date: 11 Jun 2012	Date: 11 Jun 2012
Prepared by : Nguyen Thanh Trung	Date: 11 Jun 2012

I. Scope:

This Working instruction apply for Kodama catheter product which is made in FOV.

II. SPC control parameter:

NO	Location	Caterogy/Process	Parameter	Specification	Reference document	Remark
1	Medical cleaning room	Main cleaning room enviroment control	Particle	Size's 0.5 um . Quantity < 5000 pcs/cfu.		
2			Temperature	20oC ~ 28oC.		
3			Humidity	10% ~ 90%.		
4		All heating processes	Temperature	Refer to process specificati in Operation procedure.	4-OP-345	
5		UV curing	UV power	Power ≥ 4 W/cm2		EFOS 100SS
6		Drive cable assembly	Laser power	0.0855 J ~ 0.1088J		
7	Hydrophilic coating room	Cleaning room enviroment control	Particle	Size's 0.5 um . Quantity < 5000 pcs/cfu.		
8			Temperature	18oC ~ 25oC		
9			Humidity	Below 60%		
10		Hydrophilic coating	Viscosity	20% ~ 80%	4-OP-614	
11			Moisture	-		Waiting SVMI

VI. REVISION HISTORY

REVISION HISTORY						

Date	Person	Version	Old content of description	New content		Reason of change
				New description	Change requester	
21-May-12	T.Trung	1		* Establish		