

# MATERIAL SAFETY DATA SHEET

PRODUCT NAME PEDIATRIC SCALP VEIN SET  
 COMPANY NISSHO NIPRO CORPORATION LTD.  
 ADDRESS 10/2 MOO 8 HANGNOMKO, SENA, AYUTHAYA 13110  
 THAILAND

PART NAME  
 PSV WING HUB  
 PSV LUER CONNECTOR 2.1  
 CP LUER CONNECTOR  
 PSV TUBE  
 PSV CANNULA  
 PSV PROTECTOR  
 AVF LUER CAP  
 ADHESIVE

MATERIAL NAME  
 PVC MAI-47L ( PSV WING HUB )  
 PVC MAI-47L ( PSV LUER CONNECTOR 2.1 )  
 ABS GR 1000 ( CP LUER CONNECTOR )  
 PVC MA-87HT ( PSV TUBE )  
 STAINLESS STEEL ( PSV CANNULA )  
 PE JY 4324 ( PSV PROTECTOR )  
 PP P 700 J ( AVF LUER CAP )  
 EPOXY ADHESIVE 3100 W (A), (B) ( ADHESIVE )  
 SILICONE MDX4-4159 AND 360 MEDICAL FLUID  
 12500 CS ( ADHESIVE )

SAFETY TEST PLEASE SEE ATTACHMENTS.

*Confirmed by Dr. O'Connell  
 21 Oct, '97*

TEST RESULT OF MATERIAL

ID. NO. QCL 9612-PVCT-001

1. SPECIMEN PVC MAT-471 (BT) T6RZQ4D7 (N)

LOT NO. -

2. RECEIPT DATE 17 Dec, 96

3. TESTING DATE 19 Dec, 96

4. RESPONSIBLE PERSON Ms. Rungtiwa B.

ITEM	SPECIFICATION	RESULT	EXAMINER
ML HEAVY METAL	< 10 ug/g	-	
T LEAD	< 1 ug/g	0.575	Arom A.
E CADMIUM	< 1 ug/g	Not Detected	
S <del>COPPER</del> ALUMINIUM	REFERENCE	3.762	
T TIN	< 2 ug/g	-	
E % TRANSMITTANCE (430,650 nm)	> 93 % T	99.8, 99.6	Arom A.
X APPEARANCE	COLORLESS, TRANSPARENT AND NO FOREIGN MATTER	Passed	
A PH	SAMPLE	5.06	
	BLANK	5.66	
	DIFFERENCE	0.60	
T FOAMING	< 3 mins	min 15 sec	
I HEAVY METAL	TIN	< 0.05 ug/g	
	ZINC	< 0.5 ug/g	0.118
N KMnO4	SAMPLE	19.65	
	REDUCIBLE BLANK	19.85	
T SUBSTANCES	DIFFERENCE	< 1 ml	0.20
E EVAPORATION RESIDUE	< 2 mg	0.1	
S UV ABSORBANCE 220-350 nm	< 0.1	0.021	
T RESIDUE ON IGNITION	< 5 mg	-	
TOTAL JUDGEMENT		PASSED	

TEST METHOD

MEDICAL PVC COMPOUND I  
(PRIVATE STANDARD OF MEDICAL PLASTICS)

Q.C.L SECTION / Q.C. DEPARTMENT

D = Edema

N = Necrosis

$\bar{X}$  =  $\bar{X}$  of R scores +  $\bar{X}$  of D scores

JUDGEMENT

Conformed to the official standard.

# BIOLOGICAL TEST

1/6

Date 02 Aug., 95

**SPECIMEN** PVC MAI 47 L 0003-30 RED

Lot No. -

**TEST DATE** 28 Jul., 95

**EXAMINER** Mr. Pramote K.

**EXAMINATION** Intracutaneous reactivity test of specimen

**TEST MATERIAL** Extract of sample in Sodium Chloride Injection.

**METHOD** This examination was performed by the method according to the USP 23.

**PROCEDURE** The test solution shall accord with the Intracutaneous test of the USP 23 when test in accordance with the procedures specified.

**RESULT** The experimental results are as follow;

Rabbit No.	Specimen	After test ( $\bar{X}$ )										Mean scores	Difference	
		24 hrs.			48 hrs.			72 hrs.						
		R	D	N	R	D	N	R	D	N	R			
1	S	0	0	0	0	0	0	0	0	0	0	0	S = 0	0
	B	0	0	0	0	0	0	0	0	0	0	0		
2	S	0	0	0	0	0	0	0	0	0	0	0	B = 0	0
	B	0	0	0	0	0	0	0	0	0	0	0		
3	S													
	B													

S = Sample,

B = Blank,

R = Erythema

D = Edema,

N = Necrosis.

$\bar{X} = \bar{X}$  of R scores +  $\bar{X}$  of D scores

**JUDGEMENT** Conformed to the official Standard.