

PRODUCT REGISTRATION AND LISTING

1.0 COMPANY QUALITY MANAGEMENT SYSTEM

PLEASURE LATEX PRODUCTS SDN. BHD. (hereinafter known as PLP) is an ISO 9001 (**Certification No.: GB98/13571**) and ISO 13485 (**Certificate No.: GB98/13572**) (Quality Management System for Medical Devices Manufacturer) certified company and its condom testing laboratory is accredited with ISO / IEC 17025 (**Certificate No.: SAMM 260**).

2.0 US FDA REGISTRATION PRODUCTS

PLP has registered and issued with **510 (k) Pre-Market Approval** for the following products with Food and Drug (FDA) United States for market in USA.

Device Name	Surface Texture	Width	Lubricant	Colour	Flavour	Regulation Number	Product Code	510 (k) Number	Decision Date
"SURE" Latex Ultrasonic Probe Cover	Plain	51mm	Unlubricated	Natural	-	892.1570	90 ITX	K022156	11-Sep-2003
Colored and Flavored Male Latex Condom	Smooth /Dotted / Ribbed / Contoured (3in1)	52mm / 56mm	Silicone / N-9 with PEG	RD, BL, GN, BK	ST, MT, VL, LR	884.5300 884.5310	85 HIS 85 LTZ	K023333	23-Jun-2003
Latex Condom with Dotted-Ribbed-Contoured	Dotted-Ribbed-Contoured (3in1)	53mm	Silicone (Polydimethylsiloxane)	Natural	-	884.5300	85 HIS	K021875	5-九月-2002
Male Latex Condom with Ribbed Surface	Ribbed	52mm	Silicone (Polydimethylsiloxane)	Natural	-	884.5300	85 HIS	K020272	26-四月-2002
Multiple Male Latex Condom	Plain	52 ± 2 mm	Silicone (Polydimethylsiloxane)	Natural	-	884.5300	85 HIS	K002571	16-十一月-2000
Spermicidal Lubricated Male Latex Condom	Plain	53mm	Nonoxynol-9 with Polyethylene Glycol	Natural	-	884.5310	85 LTZ	K001377	8-六月-2000
Male Latex Condom with Dotted Surface	Dotted	53mm	Silicone	Natural	-	884.5300	85 HIS	K001221	19-五月-2000
Male Latex Condom with Vanilla flavour, 56mm width	Plain	56mm	Silicone	Natural	Vanilla	884.5300	85 HIS	K994311	21-三月-2000
Male Latex Condom, 56mm	Plain	56mm	Silicone	Natural	-	884.5300	85 HIS	K994312	21-三月-2000
"SURE" Condom (Natural Rubber Latex Contraceptive)	Plain	53mm	Silicone	Natural	-	884.5300	85 HIS	K982380	26-二月-1999

FDA REGISTER

1. Registration No.: 9613994
2. Owner/Operator ID : 9032729
3. Device Listing For Non-Spermicidal Condom : E 100567
4. Device Listing For Spermicidal Condom : E 100565
5. Device Listing For Probe Cover : E 180679

COLOUR

1. RD - Red
2. BL - Blue
3. GN- Green
4. BK - Black

FLAVOUR

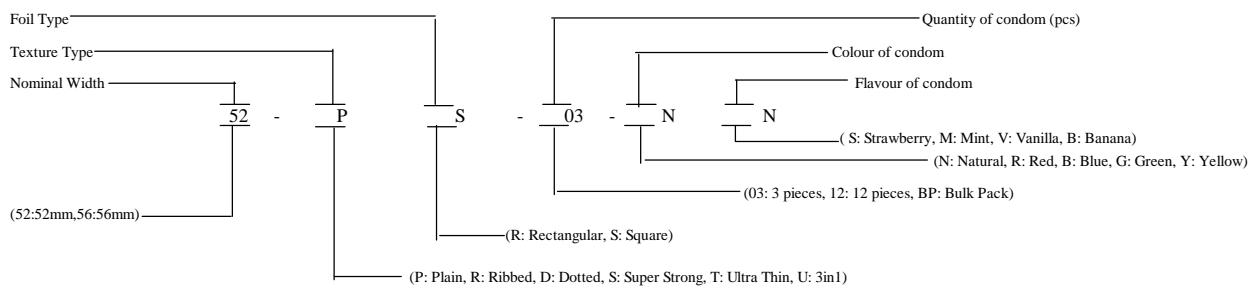
1. ST - Strawberry
2. MT - Mint
3. VL - Vanilla
4. LR - Licorice

3.0 CANADIAN MEDICAL DEVICE LICENCED PRODUCTS

The following products manufactured by PLP have been approved and listed with Canadian Medical Device Bureau for market in Canada.

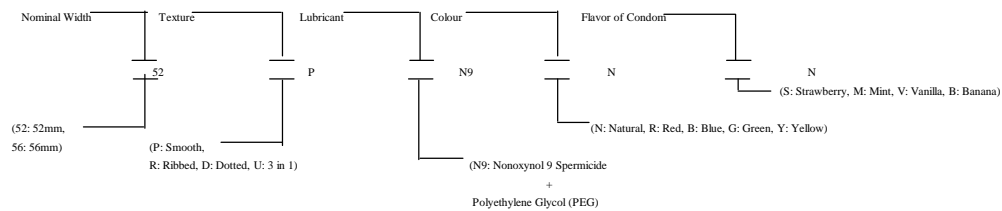
LICENCE NO. : 37003					
Name of Device : Latex Male Condom (Non-Spermicidal)					
Texture	Nominal Width (mm)	Colour	Lubricant	Flavour	Product Code
Smooth	52	Natural	Silicone Oil	-	52-PR-03-NN 52-PR-12-NN 52-PS-12-NN 52-P-BP-NN 52-PS-03-NN
Smooth	52	Red	Silicone Oil	Strawberry	52-PR-03-RS 52-PR-12-RS 52-PS-12-RS 52-P-BP-RS 52-PS-03-RS
Smooth	52	Blue	Silicone Oil	Peppermint	52-PR-03-BM 52-PR-12-BM 52-PS-12-BM 52-P-BP-BM 52-PS-03-BM
Smooth	52	Green	Silicone Oil	Vanilla	52-PR-03-GV 52-PR-12-GV 52-PS-12-GV 52-P-BP-GV 52-PS-03-GV
Smooth	52	Yellow	Silicone Oil	Banana	52-PR-03-YB 52-PR-12-YB 52-PS-12-YB 52-P-BP-YB 52-PS-03-YB
Dotted	52	Natural	Silicone Oil	-	52-DS-03-NN 52-DR-03-NN 52-DR-12-NN 52-DS-12-NN 52-D-BP-NN
Ribbed	52	Natural	Silicone Oil	-	52-RS-03-NN 52-RR-03-NN 52-RR-12-NN 52-RS-12-NN 52-R-BP-NN
3 in 1 (Dotted/ Ribbed/ Contoured)	52	Natural	Silicone Oil	-	52-US-03-NN 52-US-12-NN 52-U-BP-NN 52-UR-03-NN 52-UR-12-NN
Smooth	56	Natural	Silicone Oil	-	56-PR-03-NN 56-PR-12-NN 56-PS-12-NN 56-P-BP-NN 56-PS-03-NN
Smooth	56	Red	Silicone Oil	Strawberry	56-PR-03-RS 56-PR-12-RS 56-PS-12-RS 56-P-BP-RS 56-PS-03-RS
Smooth	56	Blue	Silicone Oil	Peppermint	56-PR-03-BM 56-PR-12-BM 56-PS-12-BM 56-P-BP-BM 56-PS-03-BM
Smooth	56	Green	Silicone Oil	Vanilla	56-PR-03-GV 56-PR-12-GV 56-PS-12-GV 56-P-BP-GV 56-PS-03-GV
Smooth	56	Yellow	Silicone Oil	Banana	56-PR-03-YB 56-PR-12-YB 56-PS-12-YB 56-P-BP-YB 56-PS-03-YB

Product Code Designation



LICENCE NO. : 39232					
Name of Device : Latex Male Condom (Spermicidal)					
Texture	Nominal Width (mm)	Colour	Lubricant	Flavour	Product Code
Smooth	52	Natural	Nonoxynol 9 + PEG	-	52-P-N9-NN
Smooth	52	Red	Nonoxynol 9 + PEG	Strawberry	52-P-N9-RS
Smooth	52	Blue	Nonoxynol 9 + PEG	Peppermint	52-P-N9-BM
Smooth	52	Green	Nonoxynol 9 + PEG	Vanilla	52-P-N9-GV
Smooth	52	Yellow	Nonoxynol 9 + PEG	Banana	52-P-N9-YB
Dotted	52	Natural	Nonoxynol 9 + PEG	-	52-D-N9-NN
Ribbed	52	Natural	Nonoxynol 9 + PEG	-	52-R-N9-NN
3 in 1 (Dotted/ Ribbed/ Contoured)	52	Natural	Nonoxynol 9 + PEG	-	52-U-N9-NN
Smooth	56	Natural	Nonoxynol 9 + PEG	-	56-P-N9-NN
Smooth	56	Red	Nonoxynol 9 + PEG	Strawberry	56-P-N9-RS
Smooth	56	Blue	Nonoxynol 9 + PEG	Peppermint	56-P-N9-BM
Smooth	56	Green	Nonoxynol 9 + PEG	Vanilla	56-P-N9-GV
Smooth	56	Yellow	Nonoxynol 9 + PEG	Banana	56-P-N9-YB

Product Code Designation



4.0 RUSSIAN MOH REGISTERED PRODUCTS

PLP manufactured condoms are registered with Russian MOH (**Registration No. 2001/872**) for market in Russia country.

5.0 EUROPEAN REGULATIONS

PLP produces various types of condom that fully comply with European Regulation- *Council Directive 93 / 42 / EEC* of 14 June 1993. Our products are certified CE Mark (**Certificate NO.: GB98/13573**) affixed and have been sold to various EU member countries, including U.K, France and Holland.

6.0 CHINA STATE FOOD AND DRUG ADMINISTRATION

PLP possessed a Registration Certificate for Medical Device (**Registration No.: SFDA(I) 20032660087, SFDA(I) 20032660061**) from China SFDA and is permitted to register in the China market.

7.0 AUSTRALIAN TGA AND NEW ZEALAND MEDSAFE LISTED PRODUCTS

PLP manufactured condoms are listed with TGA's Australian Register of Therapeutic Goods (**ARTG Listing No.: 81857 and 67853**) with **Manufacturer ENT. ID. : 29697** and New Zealand MEDSAFE **File No. : TT50-6122a** to market condoms and spermicidal condoms in Australia and New Zealand respectively.

8.0 OTHER PROMINENT MARKINGS

Beside CE Mark which enabling PLP products to flow freely among EU member states, PLP is holding the following prominent markings :-

- **NF Mark (License No.: NF 062 44/01/01)**
Pre-requisite mark to enter France market beside CE Mark
- **SABS Mark (Permit No.: 6363 / 9374)**
A must to enter South Africa market
- **SIRIM Mark (License No.: PP 035801)**
Mark granted by SIRIM QAS Sdn. Bhd. (Malaysia)
- **CCC Mark**
- Normal Smooth Rubber Condom (**Certification No.: 2003071501000063**)
- Unusual Smooth Rubber Condom (**Certification No.: 2003071501000062**)
- Textured Rubber Condom (**Certification No.: 2003071501000064**)

Certification Mark granted as China Compulsory Product Certification to enter China market.

Yours truly,
PLEASURE LATEX PRODUCTS SDN. BHD.

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