



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 11 0650 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws) certifies that the **products – Medical Devices of Class IIa**

Sterile Hypodermic Syringes for Single Use, with or without Needle
Sterile Hypodermic Needles for Single Use
Sterile Single Use Syringes, with or without Needle for Insulin

Brand Name: SAFE- PLUS

(For detailed specification refer to the annex; pages 1-2)

manufactured by the company

VEEKAY SURGICALS PVT. LTD.

D-8, Industrial Area, Bahadrabad, Haridwar – 249 402, Uttarakhand, India

are manufactured under conditions fulfilling the quality system requirements of Annex V, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex V, Sections 3.3 and 4, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601216/2011, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 28th July 2016 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 29th July 2011



RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



**Annex to EC Certificate
No. 11 0650 QS/NB**

Issued for the company:
VEEKAY SURGICALS PVT. LTD.
D-8, Industrial Area, Bahadrabad, Haridwar- 249 402, Uttarakhand, India

List of the medical devices covered by the Certificate:

Sterile Hypodermic Syringes for Single Use, with or without Needle:

Code No.	SYRINGE	NEEDLE SIZE	PACKING TYPE	PACKING INNER	PACKING OUTER
VS-01	2cc/ml-two piece	w/o, 21G ,22G 23G, 24G, 26G	BLISTER	100 Pieces	100x30=3000 Pcs 100x45=4500 Pcs
VS-02	2cc/ml-three piece	w/o, 21G ,22G 23G, 24G, 26G	RIBBON	100 Pieces	100x30=3000 Pcs
VS-03	2cc/ml-three piece	w/o, 21G ,22G 23G, 24G, 26G	BLISTER	100 Pieces	100x30=3000 Pcs
VS-04	3cc/ml-three piece	w/o, 21G ,22G 23G, 24G, 26G	RIBBON	100 Pieces	100x20=2000 Pcs
VS-05	3cc/ml-three piece	w/o, 21G ,22G 23G, 24G, 26G	BLISTER	100 Pieces	100x30=2000 Pcs
VS-06	5cc/ml-three piece	w/o, 21G ,22G 23G, 24G, 26G	RIBBON	100 Pieces	100x20=2000 Pcs
VS-07	5cc/ml-three piece	w/o, 21G ,22G 23G, 24G, 26G	BLISTER	100 Pieces	100x20=2000 Pcs
VS-08	10cc/ml-three piece	w/o, 21G ,22G 23G	RIBBON	50 Pieces	50x20=1000 Pcs
VS-09	10cc/ml-three piece	w/o, 21G ,22G 23G	BLISTER	50 Pieces	50x20=1000 Pcs
VS-10	20cc/ml-three piece	w/o, 21G ,22G 23G	RIBBON	25 Pieces	25x20=500 Pcs



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Valid until 28th July 2011

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VEEKAY SURGICALS PVT. LTD.
D-8, Industrial Area, Bahadrabad, Haridwar– 249 402, Uttarakhand, India

List of the medical devices covered by the Certificate:

VS-11	50cc/ml-three piece	w/o, 21G ,22G	RIBBON	25 Pieces	25x16=400 Pcs
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Sterile Hypodermic Needles for Single Use:

Code No.	ITEM	LENGTH HUB	COLOUR	PACKING INNER	PACKING OUTER
VN-01	26 G (0.45 mm)	½ " (13 mm)	Brown	100 Piece	100x100=10000 per box
		1 ½ " (38mm)		100 Piece	100x60=6000 per box
VN-02	24 G (0.55 mm)	1" (25mm)	Medium Purple	100 Piece	100x100=10000 per box
		1 ½ " (38mm)		100 Piece	100x60=6000 per box
VN-03	23 G (0.63mm)	1" (25mm)	Deep Blue	100 Piece	100x100=10000 per box
		1 ½ " (38mm)		100 Piece	100x60=6000 per box
VN-04	22 G (0.71mm)	1" (25mm)	Black	100 Piece	100x100=10000 per box
		1 ½ " (38mm)		100 Piece	100x60=6000 per box
VN-05	21 G (0.80 mm)	1" (25mm)	Deep Green	100 Piece	100x100=10000 per box
		1 ½ " (38mm)		100 Piece	100x60=6000 per box
VN-06	20 G (0.90 mm)	1" (25mm)	Yellow	100 Piece	100x100=10000 per box
		1 ½ " (38mm)		100 Piece	100x60=6000 per box
VN-07	18 G (1.20 mm)	1" (25mm)	Pink	100 Piece	100x100=10000 per box
		1 ½ " (38mm)		100 Piece	100x60=6000 per box

Sterile Single-Use Syringes with or without Needle for Insulin:

Code No.	INSULIN SYRINGE	NEEDLE SIZE	PACKING TYPE	PACKING INNER	PACKING OUTER
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D-8, Industrial Area, Bahadrabad, Haridwar– 249 402, Uttarakhand, India

List of the medical devices covered by the Certificate:

VI-01	1 cc/ml U-40	28 G (0.35 mm) 29 G (0.33 mm) 30 G (0.30 mm)	MULTI UNIT PACKING	10 x 10 = 100 Pcs/case	100 x 20=2000 per box
VI-02	1 cc/ml U-40	28 G (0.35 mm) 29 G (0.33 mm) 30 G (0.30 mm)	SINGLE UNIT RIBBON PACK	1 x 100 = 100 Pcs/case	100 x 30=3000 per box
VI-03	1 cc/ml U-100	28 G (0.35 mm) 29 G (0.33 mm) 30 G (0.30 mm)	MULTI UNIT PACKING	10 x 10 = 100 Pcs/case	100 x 20=2000 per box
VI-04	1 cc/ml U-100	28 G (0.35 mm) 29 G (0.33 mm) 30 G (0.30 mm)	SINGLE UNIT RIBBON PACK	1 x 100 = 100 Pcs/case	100 x 30=3000 per box



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