



EVPU®

NOTIFIED BODY No. 1293

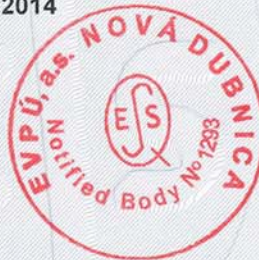
EC CERTIFICATE PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical devices, Annex V,
transposed into "Slovak government decree No. 572/2001 Coll. of Laws" as amended

No. 40020/101/1/2009/CE

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.. Identification of the products covered by this certificate is given in the Appendix.

Manufacturer and Facility	SURETECH MEDICAL INC. 333, Khurana compound, I.B. Patel Road, Goregaon (East) Mumbai, 400 063 India
Applicant	SURETECH MEDICAL INC. 333, Khurana compound, I.B. Patel Road, Goregaon (East) Mumbai, 400 063 India
Product(s)	Medical disposables – Surgical Accessories for Cardiology, Nephrology, Radiology, Urology
Product type(s)	see Annex 1
Classification of medical device	Medical Devices – Class IIa
Scope of quality system	Quality of production, storage and distribution
Final report number	40020/2009/C
Date of issue	June 8th, 2009
Date of the end of validity	June 7th, 2014



Karol Glamoš



The **CE** Marking may only be used if all relevant and effective Directives of EP and Council are complied with.

The Notified Body has audited the quality system in accordance with the Directive 93/42/EEC Annex V (3) and found that the quality system meets the requirements in the Directive 93/42/EEC Annex V.

The placing on the market of Class IIb and Class III devices covered by this certificate an EC type-examination certificate according to the Directive 93/42/EEC Annex III is required.

The manufacturer must inform EVPU a.s. of any plan for substantial changes in the design, construction of the products or the quality system of production in order to examine whether this Certificate remains valid. Annual Surveillance Audits will be held to verify the validity of this Certificate.

This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive 93/42/EEC may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with the Directive 85/374/EEC.

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Annex 1 to Certificate No. 40020/101/1/2009/CE

Details of product:

a) Cardiology products

Introducer Needle	18G *7 cm, 20G * 4 cm, 21G * 4 cm
PTFE Coated Guidewire (TEFLON COATED):	a). 150 cm (0.035 & 0.038) (J TIP / Straight) b). 260 cm (0.035 & 0.038) (JTIP / Straight) c). 150 cm (0.025 & 0.028/0.032) (JTIP / Straight)
Y Connector	9F
Torque device	Device handle: Green, Yellow and Orange
Insertion tool	
Angio kit	Y Connector, Torque Device, Insertion Tool
Manifold (2 PORT/ 3 PORT)	(Right Off / Right on)
Control Syringe	12 ml
High Pressure Stop Cock	1200 PSI

b) Dialysis products

Automatic Biopsy Gun	14G, 16G, 18G, (10 cm /15 cm / 20 cm / 25 cm)
Semi Automatic Biopsy Gun	14G, 16G, 18G, & 20G (09 cm / 15 cm / 20 cm)
Biopsy Needle	14G, 16G & 18G (08 cm / 11 cm / 15 cm)
Core Biopsy Replacement Needle	14G, 16G & 18G (16 cm, 20 cm & 25 cm)
Stainless Steel Guidewire	80 cm (0.035 & 0.038) (J TIP / Straight)
Single Lumen Femoral Catheter	14G * 13.5 cm

c) Radiology products

Three part needle	18G (15 cm / 23 cm)
Breast localisation needle	20G (7 cm, 10 cm & 15 cm)
Chiba needle	(18G, 20G, 22G & 23G) (15 cm / 22 cm)
Aspiration Needle	(16G, 18G, 20G & 22G)



d) Urology products

Double "J" Stent (Open & Closed End)	(3, 4, 4.5, 5, 5.5 & 6F) (12 cm to 28 cm)
Pigtel (PCN Catheter)	(7, 8, 9, 10 & 12F) (22 & 30 cm)
Pigtail with Trocar	(7, 8, 8.5, 9, 10 & 12F) (22 & 30 cm)
Ureteral Catheter (Open End & Closed End)	(3,4,5, 6, & 7F) 70 cm
One Step Dilator (Nottingham)	(6-12, 7-14)
Tur Cutting Loop	A) Single Stamp (24F / 27F) B. Double Stamp (24F / 27F)
Endoplotomy Stent	(6-12,7-14) (26 cm)
Ziro Tip Nitinol Basket	3F/4F/5F (70 cm / 90 cm / 120 cm)
Fascial Dailator Set	(6F-16F)
Malecot Catheter	(10F, 12F, 14F, 16F & 18F)



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