



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

EC CERTIFICATE

No. 10 0847 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 Disposable Medical Devices

(For detailed list refer to Annex to this Certificate)

manufactured by company

Mediplus (India) Limited

1261-1262 M.I.E., Part –B, Bahadurgarh 124 507, Haryana, INDIA

are manufactured under conditions fulfilling the quality system requirements of Annex II, 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 II, Sections 3.3. and 5., 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. 803600988/2010, 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 14th October 2015 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 15th October 2010



Paul Voj

RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023



Annex to EC Certificate No. 10 0847 QS/NB

Issued for the company:

Mediplus (India) Limited

1261-1262 M.I.E., Part –B, Bahadurgarh 124 507, Haryana, INDIA

List of the medical devices covered by the EC certificate:

Product	Range	Classification
I.V. Cannula	10G, 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G & 26G	IIa
I.V. Cannula with Safety Feature	10G, 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G & 26G	
3-Way Stop Cock	Blue, Red & White Tap	
3-Way Stop Cock with Extension Tube	10cm, 50cm, 100cm, 150cm, 200cm, 250cm	
A.V. Fistula Set / Needle	15G, 16G, 17G	
Injection Stopper	With or without Latex	
Male – Female Luer Lock	-	
Luer Lock	-	
Pressure Monitoring Tube	10cm, 50cm, 100cm, 150cm, 200cm, 250cm	

Issued in Zlín, on 15th October 2010
Valid until 14th October 2015



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