



NOTIFIED BODY No. 1023
Institute for Testing and Certification, Inc., Zlín, Czech Republic

EC Design-Examination Certificate

No. 07 0140 CN/NB

issued in compliance with Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 Coll., certifies that the product – medical device of Class III

Hydrocefalus Shunt “Chhabra Z Flow” and accessories

(For detail specification refers Annex, page 1 and 2)

manufactured by

G . Surgiwear Limited

Rasoolpur Jahangunj, Shahjahanpur-242001, U.P., INDIA

Id. No.: 3/SC/P of 1995 and 37 of 1997

Tax registration id.: LKNG05137G

fulfils the essential requirements specified in the Annex I of the Directive 93/42/EEC relating to it, taking into account the product's intended use.

The Notified Body No. 1023 has executed the EC design-examination of the above-mentioned product according to Article 4, Annex II of the Directive 93/42/EEC. The detailed product descriptions, documents, assessment procedures and evaluation of the examination are presented in the ITC's Final Report No. 803600175/2007.

This Certificate is issued under following conditions:

1. *It applies only to the design of above referenced model of medical device.*
2. *It does not imply that the Notified Body has performed any surveillance or control of its manufacture.*
3. *The Certificate remains valid until the approved design is changed but until the **20th March 2012** at the latest.*
4. *Having in possession a complementary EC Certificate confirming the manufacturer's quality system approval by Notified Body No. 1023, the manufacturer shall affix to each medical device of this type the conformity CE marking followed by number of Notified Body according to an example:*

CE 1023

Issued in Zlín, on 21st March 2007



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

Annex to EC Design Examination Certificate No. 07 0140 CN/NB

issued for the company:

G. Surgiwear Limited

Rasoolpur Jahangunj, Shahjahanpur-242001, U.P., INDIA

Id. No.: 3/SC/P of 1995 and 37 of 1997

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List of Types covered by the EC certificate:

Product type:	Model:	Code No.
Hydrocephalus Shunt Chhabra Z Flow complete set	Two ball system	SH101
	Three ball system	SH102
	Four ball system	SH103
Chabra 'Slit n Spring' Hydrocephalus Shunt System complete set regular size	VP High Pressure	SH201
	P Med Pressure	SH202
	VP Low Pressure	SH203
	VA High Pressure	SH204
	VA Med Pressure	SH205
	VA Low Pressure	SH206
Chhabra 'Slit in Spring' Hydrocephalus Shunt System with large Flushing reservoir complete set Adult size	VP High Pressure	SH231
	VP Med Pressure	SH232
	VP Low Pressure	SH232
GSL "Dome Valve" Hydrocephalus Shunt System	High Pressure	SH601
	Medium Pressure	SH602
	Low Pressure	SH603
Chhabra Lumber Peritoneal Shunt System	With Touhey Needle	SH301
	Without Needle	SH302
Chhabra 'Z'Flow valve only	Two balls type	SH111
	Three balls type	SH112
	Four balls type	SH113
Chhabra 'Slit n Spring' valve only	High Pressure	SH211
	Medium Pressure	SH212
	Low Pressure	SH213
Chhabra 'Slit in Spring" valve with large flushing reservoir	High Pressure	SH221
	Medium Pressure	SH221
	Low Pressure	SH223

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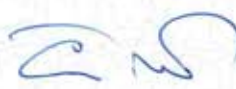
List of Types covered by the EC certificate: (continued)

Product type:	Model:	Code No.	
Uni Shunt	High Pressure	SH401	
	Medium Pressure	SH402	
	Low Pressure	SH403	
	Custom		
Aqueductal Stent	Small	SH501	
	Medium	SH502	
	Large	SH503	
Parts	Distal 90 cm long	SH001	
	Ventricular 15 cm length	SH002	
	Lumber Part	SH009	
	Custom		
Connectors	Straight	SH003	
	Right angle	SH004	
	Connector for LP Shunt	SH005	
	'Y' Connector with extra large ventricular Part	SH006	
	Suture Collars	SH007	
	Ante Chamber	SH008	
	Cranial Flap anchor	SH009	
	Cerebral Reservoir	Small	SH011
		Large	SH012

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