



Medicines & Healthcare products
Regulatory Agency

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Medicines and Healthcare Products Regulatory Agency

On behalf of the Department of Health

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS TO

THAILAND

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by; *****Medical Co.,Ltd.**, *** Road, ***, PEOPLE'S REPUBLIC OF CHINA, have been affixed with the CE mark under the Medical Devices Directive 93/42/EEC as transposed into UK legislation (UK Medical Devices Regulations 2002 SI No. 618, as amended), and therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.

See attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

Deanna Brownlie

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA



Schedule of Devices requested for ord-20170120-063226-pgrk

Ordered on

93/42/EEC

Directive/Class

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Mfr Name

www.isosh.com

#	Product	Make	Model	Class	UMDNS Code
1	Single-use Stone Extraction Catheter	***Medical Co.,Ltd	QS series	II a	16429
2	Single-use Balloon Dilatation Catheter	*** Medical Co.,Ltd	KZ04 series KZ06 series KZ08 series KZ10 series KZ12 series KZ15 series KZ18 series KZ20 series KZ25 series KZ30 series	II a	16429
3	Single-use Stone Retrieval Basket	***Medical Co.,Ltd	LOB series LMB series LNB series	II a	16429
4	Single-use Biliary Draining Tubing	Medical Co.,Ltd	WL series WD series WC series CL series CD series CC series	II a	10696
5	Ligation Device	Medical Co.,Ltd	Loop series LD series Loop-LD series	II a	17785
6	Sphincterotome	Medical Co.,Ltd	SD series ST series PD series PT series	II b	58813 (GMDN Code)
7	Polypectomy Snares	Medical Co.,Ltd	L16C series L16R series	II b	58813 (GMDN Code)
8	Single-use Nitinol Stone Retrieval Basket	Medical Co.,Ltd	L1310 series L1320 series L1325 series L1330 series	II a	15629
9	Single-use Nasal Biliary Drainage Catheter	Medical Co.,Ltd	α type series Reverse α type series Pigtail type series Pigtail α type series Pigtail reverse α type series Short α type series	II a	10696



10	Single-use Guidewire	Medical Co.,Ltd	L0218 series L0225 series L0235 series L0238 series	II a	11925
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Legal manufacturer:

***Medical Co.,Ltd.

***, PEOPLE'S REPUBLIC OF CHINA

End of schedule. No additional information past this point.

