

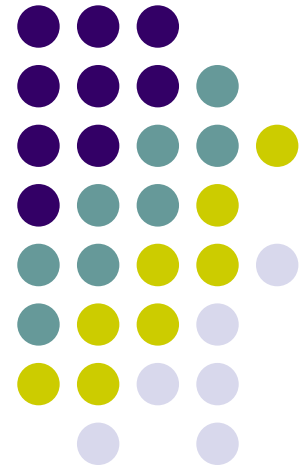
Direct Trade

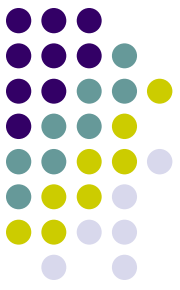
-from a manufacturer's perspective

从生产商的角度看直接贸易

Nov. 7 2006

Zhenxiu Wang 王振修
Marketing Director
Qingdao Double Butterfly Group, China
青岛双蝶集团股份有限公司



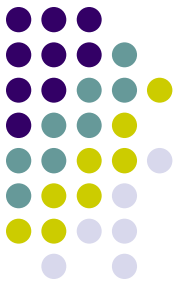


Background 背景

- Increased budget for RH commodities
- 生殖健康产品的预算增加
- Donors are seeking for a bigger impact
- 捐助方寻求更大的影响面
- Opportunities for manufactures in developing countries. Not all are aware of this.
- 对发展中国家的生产商是很好的机遇，但并不是所有的都意识到这一点。
- Direct trade challenges
- 直接贸易的挑战



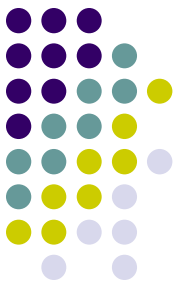
Procurement information 采购 信息



- Prequalification takes time (questionnaire, samples compliance testing, factory audit)
- 资格预审需要时间（问卷调查、样品符合性检测、验厂）
- Procurement cycles span from 1 year up to 3 years. No missing is affordable.
- 采购周期1 - 3年，一旦错过，就没有在该周期内供货的机会。
- Some organization/agent (such as UNFPA) publish the info on their own websites, others not.
- 有些机构（如UNFPA）在其网站上直接公布采购信息，有些不。
- **Information accessibility and transparency are important to manufacturers.**
- 因此采购信息的可及性和透明对生产商特别重要！



Appropriate marketing model for direct trade 直接贸易的营销模式



- Vendors are not necessarily manufacturers.
- 供应商并非都是生产商
- Vendors offer financial and communication facilities to the manufactures.
- 供应商为生产商提供资金和交流的便利
- Manufactures from developing countries usually sell to the vendors which resell to agencies.
- 发展中国家的生产商通常将产品销售给供应商，然后由其销售给发展机构



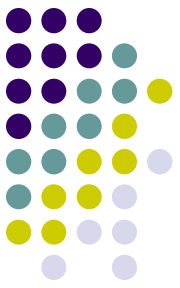
Appropriate marketing model for direct trade 直接贸易的模式



- From a long-term review, direct trade shall be encouraged for a sustainable supply of quality products.
- 从长远观点来看，应鼓励直接贸易以使高质量产品的供应可持续发展
 - Reduced risk 风险的降低
 - Increased margin for manufactures 生产商利润空间的增加
 - Reduced price for the buyer 采购价格的下降
- Some public procurement projects already required that the eligible vendor/supplier must be the manufacturer.
- 一些公共采购项目已经明确要求其供应商必须是生产商



Appropriate marketing model for direct trade 直接贸易模式



- Manufacturers' active international marketing efforts shall be strengthened
- 生产商应主动加强国际营销工作
 - Direct communication 直接的交流
 - Professional trade team 建立专业的贸易团队
 - International promotion of company and products 对公司和产品的国际推广



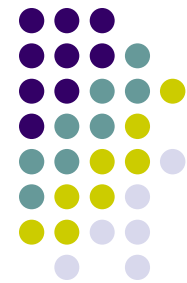
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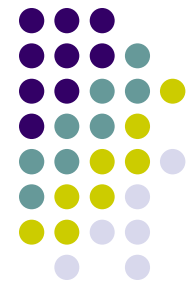
- Employee-owned company, 50 years condoms production history.
- 员工持股公司，50年的安全套生产历史。
- In 1999, QDBG began to supply condoms UNFPA via trade agencies. Lack of Information and expertise.
- 从1999年开始，青岛双蝶通过中间机构向联合国人口基金供应安全套产品。缺少国际采购信息。
- Over the past few years, efforts have been made on the following:
- 在过去的几年中，做出以下努力：
 - Tracking and applying latest international standards
 - 跟踪并采用最新的国际标准
 - International Technical Assistance 国际技术支持
 - Promote direct trade with key development agencies
 - 积极推动与主要发展机构的直接贸易



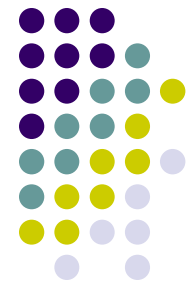
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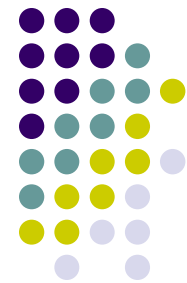
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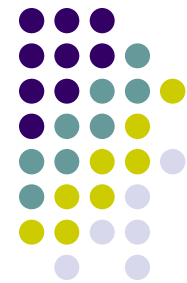
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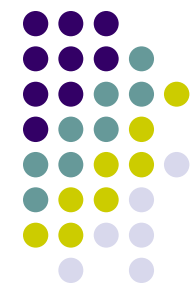


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EC Certificate

No.: G1 03 02 49194 001

TÜV
PRODUCT SERVICE

Decision according to Annex I of Council Directive 93/42/EEC concerning medical devices.

The Certification Body of TÜV PRODUCT SERVICE certifies that

Qingdao Double Butterfly Group Co., Ltd.
No. 103, Taishang 1st Road, Qingdao City
266022, Shandong, P. R. China

with the authorized EC representative

Shige Oost B.v.
Havelsloot 15A 021
550 DRONTEN
THE NETHERLANDS

in the facility (ies)

Qingdao Double Butterfly Group Co., Ltd.
No. 103, Taishang 1st Road, Qingdao City
266022, Shandong, P. R. China

for the product(s)/product category(ies)

Condom and Medical Gloves

operates a quality system in the manufacturing process, which ensures the conformity with the type described in the technical documentation.

Relevant assessment see audit report no. 70105440

Provided the agreed periodical surveillance is carried out, this certificate is valid until 2007-08-31

Referenced with the above mentioned certificate number by the Certification Body of TÜV PRODUCT SERVICE.



Department: MWS022V 431-001
Date: 2006-08-31
Authorisation No. 0103-0001

TÜV PRODUCT SERVICE GMBH - Zertifizierungsstelle - Röhrenstrasse 65 - D-82038 München

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAZIONE • CERTIFICAZIONE

CERTIFICATE

No.: Q1N 05 09 49194 004

TÜV
Product Service

Holder of Certificate: **Qingdao Double Butterfly Group Co., Ltd.**
No. 103, Taishang 1st Road
266022 Qingdao
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): **Qingdao Double Butterfly Group Co., Ltd.**
No. 103, Taishang 1st Road 266022 Qingdao, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Condom, Medical Gloves and Rubber Transfusion Tubes**

Applied Standard(s): **ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements for regulatory purposes**

The Certification Body of TÜV Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standards. See also scope number

Report No.: 7010510004
Valid until: 2008-08-31

Date: 2006-08-31
Page 1 of 1



TÜV Product Service GmbH
Röhrenstr. 65 • 82038 München
München • Tel. 089 23699-0
Germany

Akkreditiert durch
DAkkS
Zertifizierungsstellen
München Nr. 0103-0001
20.03.2005-30.09.10-04

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFICAZIONE • CERTIFICAZIONE

CERTIFICATE

The Certification Body of TÜV Management Service GmbH certifies that

Qingdao Double Butterfly Group Co., Ltd.
No. 103, Taishang 1st Road
PRC-266022 Qingdao

has established and applies a Quality Management System for

Design and Development, Production and Distribution of Condom, Medical Gloves and Rubber Transfusion Tubes

An audit was performed, Report No. 70105440
Proof has been furnished that the requirements according to

ISO 9001: 2000

are fulfilled. The certificate is valid until 2008-08-31
Certificate Registration No. 12 100 26417 TMS



March 2006-09-11

TÜV Management Service GmbH - TÜV 200 Group - Zertifizierungsstelle - Röhrenstrasse 65 - 82038 München - Germany

9/24/01 MIN 09:14 FAX 301 443 8209 FDA CERH CODE P03 Q001

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
820 Corporate Boulevard
Rockville MD 20850

SEP 21 2001

Qingdao Shang Die Latex Production Co., Ltd. Re: K012653
% Mr. Eli J. Carter
Caretaker to Qingdao Shang
1219 Little Creek Road
DURHAM NC 27713

Trade/Device Name: Male Latex Condom
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: 85 HHS
Dated: August 8, 2001
Received: August 13, 2001


Dear Mr. Carter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 899. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QSR) for Medical Devices. General regulation (21 CFR Part 820) and that, through periodic QSR inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the QSR regulation may result in regulatory actions. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: This response to your premarket notification submission does not affect any obligation you might have under sections 511 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed



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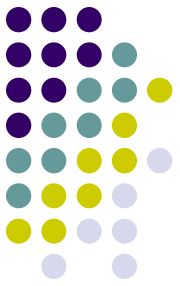
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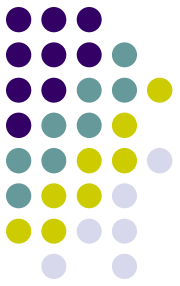


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- The realization of direct trade needs efforts both from development/procurement agencies and manufacturers.
直接贸易的实现需要发展机构和生产商共同努力。

- While we are providing quality products and services to the current clients, we are looking forward to serving more international clients and dedicated to the RH improvement in China as well as worldwide.

在我们向现有客户提供高质量的产品和服务的同时，也期待着服务于更多的国际客户，为中国乃至世界的生殖健康事业发展贡献自己的力量！



THANKS 谢谢！



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