Better Quality & more...

BQ+ 必趣医疗

FQAs for doing business with BQ+

Updated 2020.02.18

Dear customer,
Thank you very much for your interest in products and services of BQ+ Medical. In order to enable us to cooperate more efficiently, we have prepared a Frequent Question & Answer list as following:

1. How can I get information about BQ+ products and services?
2. Is BQ+ a reliable manufacturer of medical products?
3. What information do I need to provide to help BQ+ team understand my needs?
4. May I ask for samples? May I use these samples on patients?
5. How to ensure the safety of material used for BQ+ products?
6. How are the products packed? Is the packaging validated?
7. How do BQ+ guarantees the quality?
8. Could BQ+ do EO sterilization? Is your EO sterilization reliable?
9. How is the logistics and storage of BQ+ controlled?
10. How does BQ+ ensure product traceability?
11. How do I know the order status and quality level before shipment?
12. What if there were quality issues after I received the shipment?

If you have any other questions, please feel free to contact our sales representatives.

Thank you and best regards
BQ+ team

1. How can I get information about products and BQ+ company?

Please feel free to ask BQ+ sales representative for the following:

- Catalogue
  - E-catalogue
  - hard copy of catalogue

- Website: www.bq-medical.com
  www.bqplusmedical.com
  These 2 IP links to same website.

- Presentation
  - Cooperation presentation
  - Product presentation

2.1 Is BQ+ a reliable manufacturer of medical products?

2.1 BQ+ has the following certificates and registrations:


Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

NELSON Techno Medical Co., Ltd.
No. 18, Che Ye Road, Che Dun Town
Songjiang
201611 Shanghai
China

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

ISO13485: 2016


EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60105359 0001
Report No.: 15080761 001

Manufacturer: NELSON Techno Medical Co., Ltd.
No. 18, Che Ye Road, Che Dun Town
Songjiang
201611 Shanghai
China

Products: Medical Devices

Expiry Date:

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

93/42/EEC Annex V


Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

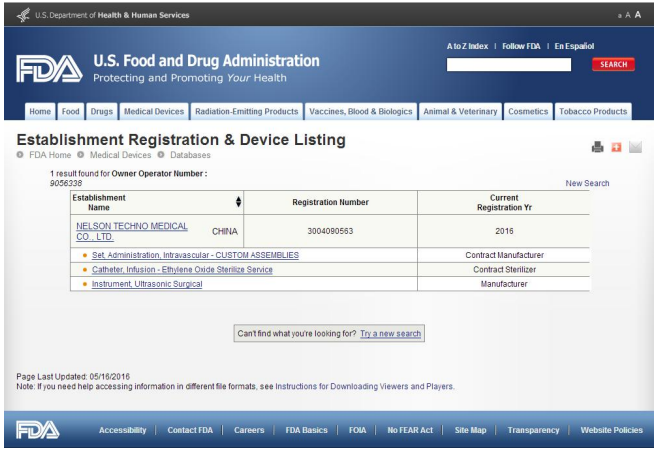
NELSON Techno Medical Co., Ltd.
No. 18, Che Ye Road, Che Dun Town
Songjiang
201611 Shanghai
China

Manufacture and Distribution of Medical Devices
(see attachment for products included)

EN ISO 9001:2008

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

ISO11135: 2014



ENISO13485:2016:
SX601277200001,

CE certificate:
DD601402690001,

FDA listed for Ethylene Oxdie Sterilize service, Manufacturer IV extension set, IV infusion set Anesthetic Mask, Liquid Medication Dispenser

KFDA Certificate of GMP for syringe or needle,

ANVISA register ID for Anesthesia Face Masks:
81504790055

2.2 Is BQ+ a reliable manufacturer of medical products?

2.2 Supplier Audit is essential to become qualified suppliers of big Medical groups. We passed every audit ever since, here are some examples of Audit reports..

Document Number: SOP-00026-F-00001	Revision: 4	Page 1 of 12
Document Title: Supplier Audit Report		

MEDLINE

Supplier Audit Report

Date: 5/16/2019

MOOG MEDICAL DEVICES GROUP | TITLE: | **SUPPLIER AUDIT PLAN**

Date of audit:	May 22th & 23th, 2019
Supplier Name:	BQ Medical Co, Ltd. Facility: No. 18 Cheye Road, Chedun Town, Songjiang District, Shangai, 201611, China.
Audit Type:	Special Audit
Audit Objective:	Verify the compliance of the applicable requirements and the effectiveness of BQ Medical's Quality System and Process Controls.
Auditor (s):	Luis Jiménez
Schedule:	1. 05/22/19; 08:30 to 17:00 2. 05/23/19; 08:30 to 16:00
Audit criteria and	ISO 13485: 2016

Kinetic | 上海凯利泰医疗科技股份有限公司 | Shanghai Kinetic Medical CO., Ltd.

编号：RE-KMC/ZD/7.4-02-05 版本：A/0

KMC 受控

供方质量管理体系审核报告

NO.: KMC20190823-01

Supplier Evaluation Audit

smiths medical
bringing technology to life

Conclusion: 结论

Smiths Medical would like to thank the BQ plus team for the preparation of the audit. And very great support during whole audit process.
史密斯医疗非常感谢必趣医疗团队对本次审核的准备，及在审核过程中的大力支持。

No SCAR has been issued as a result of the Smiths Medical Supplier Audit.
本次审核中没有形成 SCAR 项（没有严重不符合）。

TrueCare | **SUPPLIER AUDIT**

Issued by: QA	Date: 12/1/17	Revision: D	QF-016

DATE OF AUDIT: 2019.05.27-28

TYPE OF AUDIT: ■Supplier completed ____ ☐ TrueCare Biomedix completed ____

AUDIT PERFORMED BY: _____

1. GENERAL INFORMATION:

Company Name: BQ Plus Medical Co., Ltd.

Address: No. 18, Cheye Rd, Chedun Town, Songjiang District, Shanghai, 201611, China

截图(Alt + A)

Phone: +86 021-57609106 *822

Contact Name: Charles Zou

E Mail address of Primary Contact: Charles@bq-medical.com

2.3 Is BQ+ a reliable manufacturer of medical products?

2.3 We maintain a friendly and close interaction with our global customers.

2.4 Is BQ+ a reliable manufacturer of medical products?

2.4 We are manufacturing for the world famous medical groups.

3. Quotes & 4. Samples

3. What information do I need to provide to help BQ+ partners understand my needs?

Would you please let us know the following:

- ✓ Basic information about your company
- ✓ What you are buying this product for
- ✓ Annual purchase quantity
- ✓ When would you like to start the bulk supply

4. May I ask for samples? May I use samples on patients?

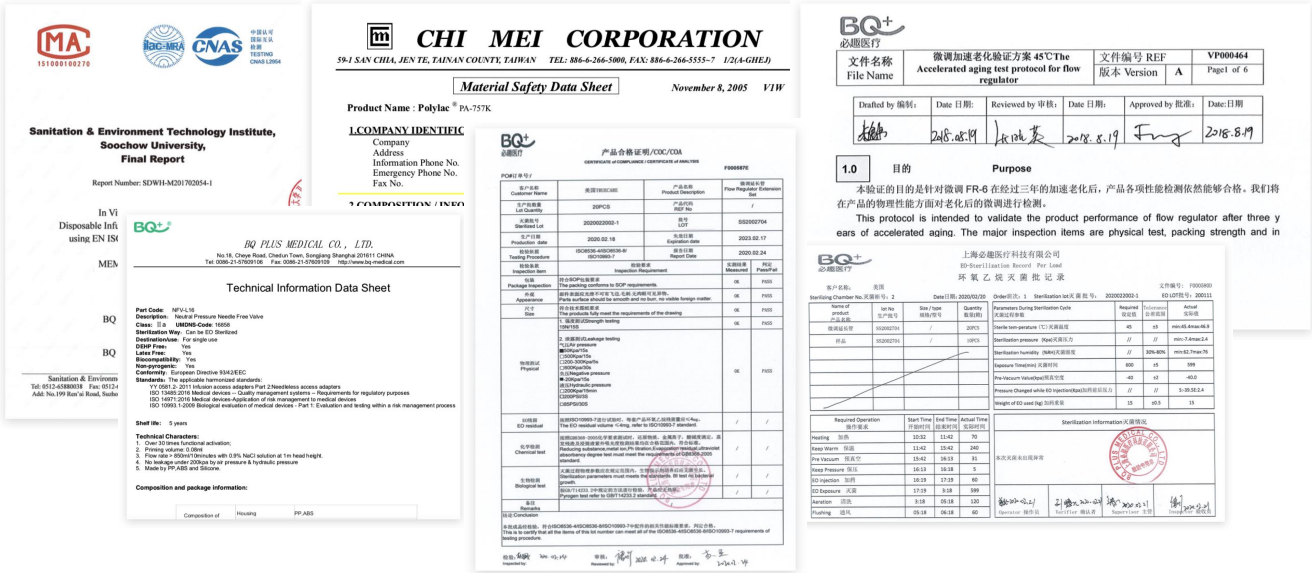
Yes, of course.

In order to save time for both of us, please first communicate with our sales representatives about the specific product specifications, configuration, technical requirements, packaging requirements and so on. We will make samples to demonstrate our understanding of your requests, and for your lab testing. We could share our test protocols and results from BQ+ lab for your reference.

Unless specifically requested, our samples are not sterilized and should not be used in clinical patients.

5. How does BQ+ ensure the safety of product?

- All raw materials have relevant technical documents, such as **MSDS, TDS**, etc
- For individual packaging, such as peal pouch and blister packing, **package validation report** will be provided.
- For sterile products, **EO Sterile validation report** will be provided.
- For registered products, there are **biocompatibility test reports**
- All products shipped are provided with **COC** and **COA**
- For registered products, can provide related **accelerated aging report, real-time aging report**, etc.



6. How are the products packaged?

Individual Pack

- Peel Pouch, Blister pack (soft & hard blister) are commonly used for good sterilization effect.

Inner pack

- Boxes and PE bags are commonly used. Qty per pack varies from products.

Outer carton

- Strong 5 - ply corrugated cartons suitable for long distance transportation.

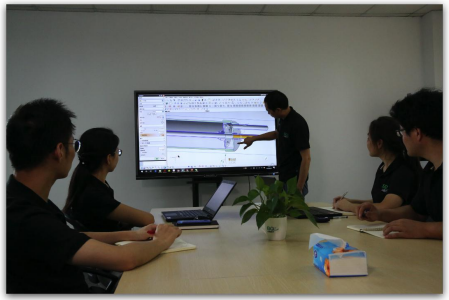
Pallet & Container

- We make pallets for LCL and wrap them with wrapping film.
- Containers are generally not palletized for the purpose of making the best use of container contents. If you have special request, we can also make pallets for your container cargoes.

7.1 How does BQ+ guarantee the quality?

7.1 Planning

Before the formal mass production of BQ products, according to the requirements of laws and regulations and the necessary **design and development process**, the product's material, structure, intended use, performance indicators and other **technical requirements** as well as the **production process** are **designed and verified**, and the **relevant technical documents** are issued through the quality management system and implemented.



7.2 How does BQ+ guarantee the quality?

7.2 In-Process Quality Control

BQ+ implements Total Quality Management. Products in the production process, including **material feeding, injection molding, extrusion, assembly, bonding, packaging, sterilization and inspection** all links, there are corresponding **production records** and **inspection records**, each process is in accordance with the corresponding **drawings, operating procedures, inspection procedures and other technical documents** for operation. Keep a detailed record of the traceability information of each project, the operation content and technical parameters of each process, and the inspection results of each technical requirement.

Total Quality Management is also reflected in the quality awareness and training level of all staff. BQ+ production and inspection personnel must undergo corresponding skill training and pass the examination before they officially take up their posts.

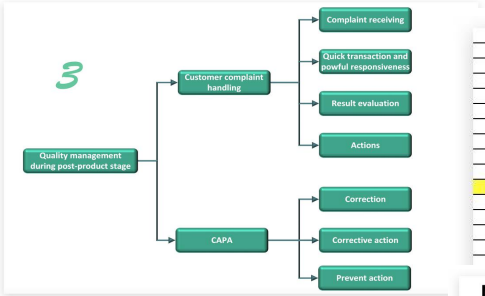



7.3 How does BQ+ guarantee the quality?

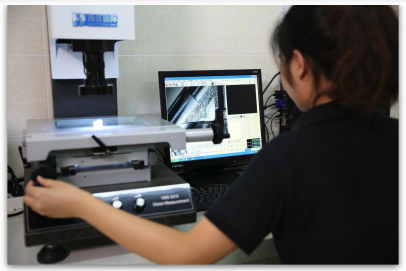
7.3 Non-conforming

The non-conforming products in the production process shall be confirmed by the quality personnel or reviewed by the responsible departments according to the document requirements and shall be repaired, reworked, scrapped and other disposal measures to ensure that all products meet the quality requirements.

Each customer feedback and complaint case will be carefully investigated and actions taken. BQ+ quality engineers on complaint handling and CAPA ability will ensure a smooth cooperation with every clients.



10/15	白班	09:30-11:30	嵌入式上盖	BZM000043	W190975103	注塑	缺料	2000	返工	11	0.55%	1	35
10/15	白班	15:30-17:30	MLL02螺旋座	BZM000013	W190975101	注塑	顶白	3000	返工	85	2.83%	1	40
10/15	白班	17:30-18:30	62无孔塑针	BZM000051	W190980303	注塑	21#拉伤	600	返工	18	3.00%	1	30
10/15	夜班	19:30-21:30	嵌入式上盖	BZM000043	W190975103	注塑	表面油污	1800	返工	30	1.67%	1	30
10/16	白班	13:30-15:30	HT102护帽	BZM000499	W190953810	注塑	缺料	3200	返工	22	0.69%	1	15
10/16	白班	13:00-14:00	72滴瓶	BZM000159	W190975110	注塑	13#发雾	3000	返工	88	2.93%	1	60
10/16	夜班	19:30-21:30	嵌入式上盖	BZM000043	W190975103	注塑	表面异物	1800	返工	45	2.50%	1	20
10/16	夜班	19:30-21:30	HT102螺旋座护帽	BZM000015	W191086602	注塑	异物	1600	返工	65	4.06%	1	15
10/17	夜班	03:30-04:30	三通阀壳	BZM000739	W190642404	注塑	9#偏芯	500	返工	27	5.40%	1	30
10/17	白班	14:00-15:00	10滴	BZM000385	W191080005	注塑	表面油污	1800	返工	13	0.72%	1	20
10/18	夜班	19:30-21:30	三通阀壳	BZM000739	W190642404	注塑	缺料	1500	返工	100	6.67%	1	60
10/19	白班	15:30-17:30	浮阀大圈	BZM000045									
10/21	白班	14:00-15:00	吊瓶塑针	BZM000054									
10/22	白班	17:30-19:30	MLL03螺旋座	BZM000014									
10/24	白班	14:00-15:00	RC101-B蓝色调节壳	BZM000021									
10/24	白班	16:30-17:30	微调下盖	BZM000698									



NC汇总评审：

一车间（ 27 次）

日期	班次	时间	产品名称	产品编号	产品批号	发生工序	不良现象描述	返工数量(PCS)	备注（及跟踪处理措施）	不良数量(pcs)	不良率	返工人数	返工工时（H）
7/3	白班	14:00-16:00	A3头部	DZM000007	BQ190640501	包装	毛发	2000	返工	1	0.1%	1	30
7/3	白班	11:30-12:30/13:00-14:00	131.15延长管	DZM000780	T-6041	包装	封口褶皱	5184	返工	3	0.1%	1	60
7/3	白班	13:30-14:30	131.05延长管	DZM000776	T-6038	包装	封口歪斜	3000	返工	2	0.1%	1	45
7/3	白班	15:30-17:30	131.08延长管	DZM000777	T-6039	包装	异物	600	返工	2	0.3%	1	30
7/3	白班	17:00-18:00	131.15延长管	DZM000780	T-6075	包装	少装每包少10pcs	900	返工	18	2.0%	1	15
7/4	白班	19:30-20:30	72滴瓶+网	DZM000168	BQ190645406	包装	缩水、变形、黑点	2200	返工	13	0.6%	1	25

投诉处理报告

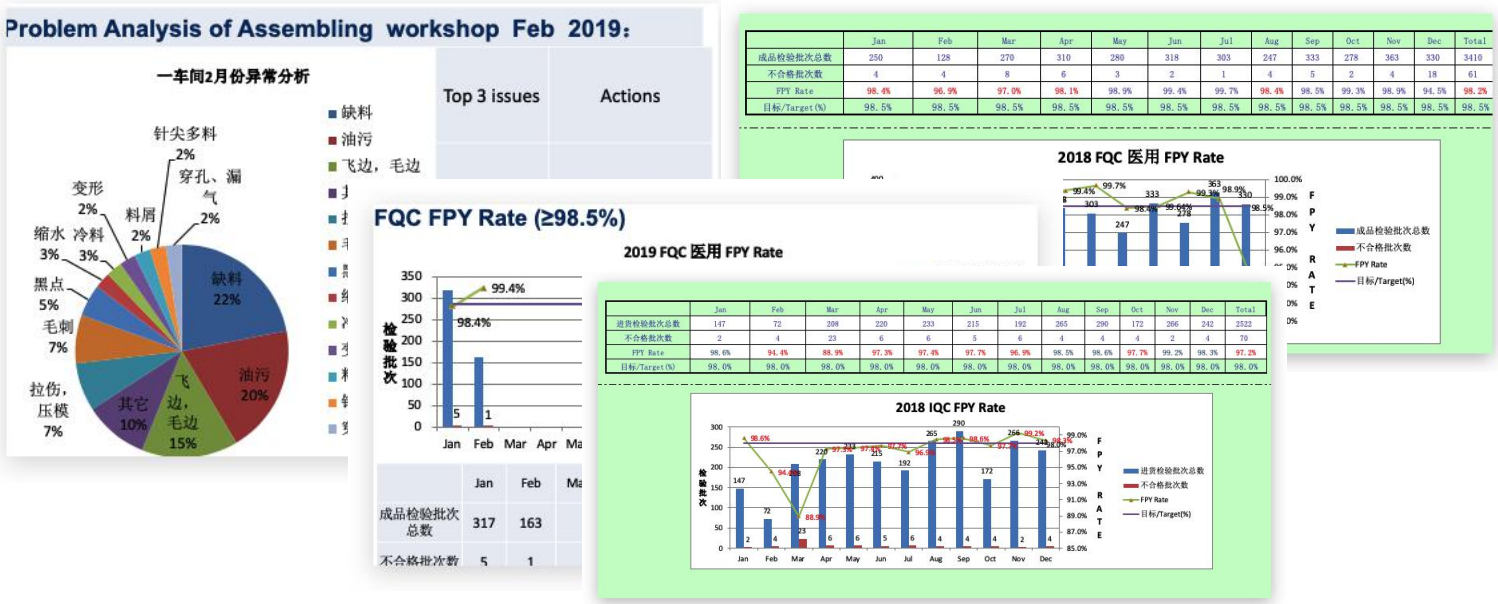
Complaint Handling Report

如涉及客户投诉请填写如下信息 For Complaint, Please fill below info:			
接收日期 Date Received	2019-11-21	投诉接收人 Received By	Colin
投诉方 Complained by	[redacted]	投诉方联系信息 Contact Info	NA
投诉方投诉编号 Customer complaint number	20191121-01	产品名称 Product Name	滴定管式输液器头部 IV Burette Set
产品编号 Product code	DZM000176	批号/生产日期 Lot #/ Mfg. Date	BQ181060503
客户投诉的问题 Customer complaints			
问题描述 Problem Description:	[redacted]客户反馈我司生产的滴定管式输液器底部漏液，批号为：BQ181060503 The [redacted] customer feedback that the bottom of IV Burette Set produced by our company leaks liquid, batch No.: BQ18160503		
原因调查 Root Cause Investigation			

7.4 How does BQ+ guarantee the quality?

7.4 Improvement

We promise a safe usage of BQ+ products by devote our sustained engagement in continuous improvement. Not only the improvement identified by our own QMS, but also the chances of improvement from our treasured clients. Every voice from you will be appreciated and considered as a valuable source of our improvement!



8. Could BQ+ do EO sterilization? Is the process reliable?

BQ+ has an independent Ethylene Oxide Sterilization Center and established the sterilization confirmation process and routine sterilization management process according to ENISO11135 standard and local additional requirements in China. BQ+ passed audit of TUV Rheinland and CFDA, and gained ENISO13485/ENISO11135 certificates. We accept the audit of domestic and foreign customers, and currently provide top sterilization confirmation service and daily sterilization service for hundreds of enterprises at home and abroad

Our customers include:

Hanex

REBONE Innovation for Health

华杰

Kynetic 凯利泰

TERESA 健康·爱心

和极实业

FULO

心瑞医疗 Heartech Medical

Delviel

Igenesis

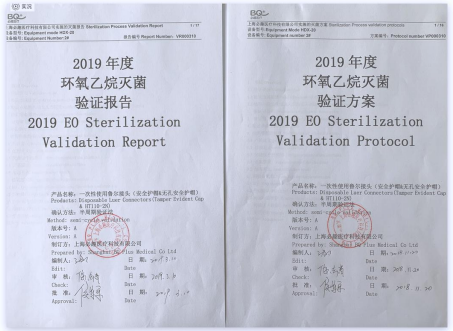
ENGINE

yuwell 鱼跃

HCP NEXT GENERATION PACKAGING

HEXAELL biotech

HANYU MEDICAL 开启瞳膜修复新时代



BQ+ provides sterile products which meets EN556-1 requirement, with a guaranteed sterility level of SAL=10^{-6}.

At the same time, BQ+ also provides commercial EO sterilization service with a complete quality system guarantee and ensured traceability. Each sterilization Service with full documentation:

- sterilization batch record
- sterilization certificate
- results of biological indicator culture
- ethylene oxide residue test result

9. How is the logistics and storage of BQ+ controled?

BQ has set up a special warehouse to store all raw materials and products. The warehouse is equipped with pest control facilities and the environment temperature is monitored.
The warehouse implements partition management for raw materials and finished products. Place raw materials or finished products according to their respective product names, specifications, models, etc., and register the traceability information of raw materials and products such as product names and batch Numbers through identification cards. The warehouse keeps information for incoming and outgoing materials and products, and carries out dynamic management.
All products shall be inspected by quality personnel and confirmed to be qualified before being put into storage. The warehouse arranges the delivery according to the shipping instructions of the sales department.





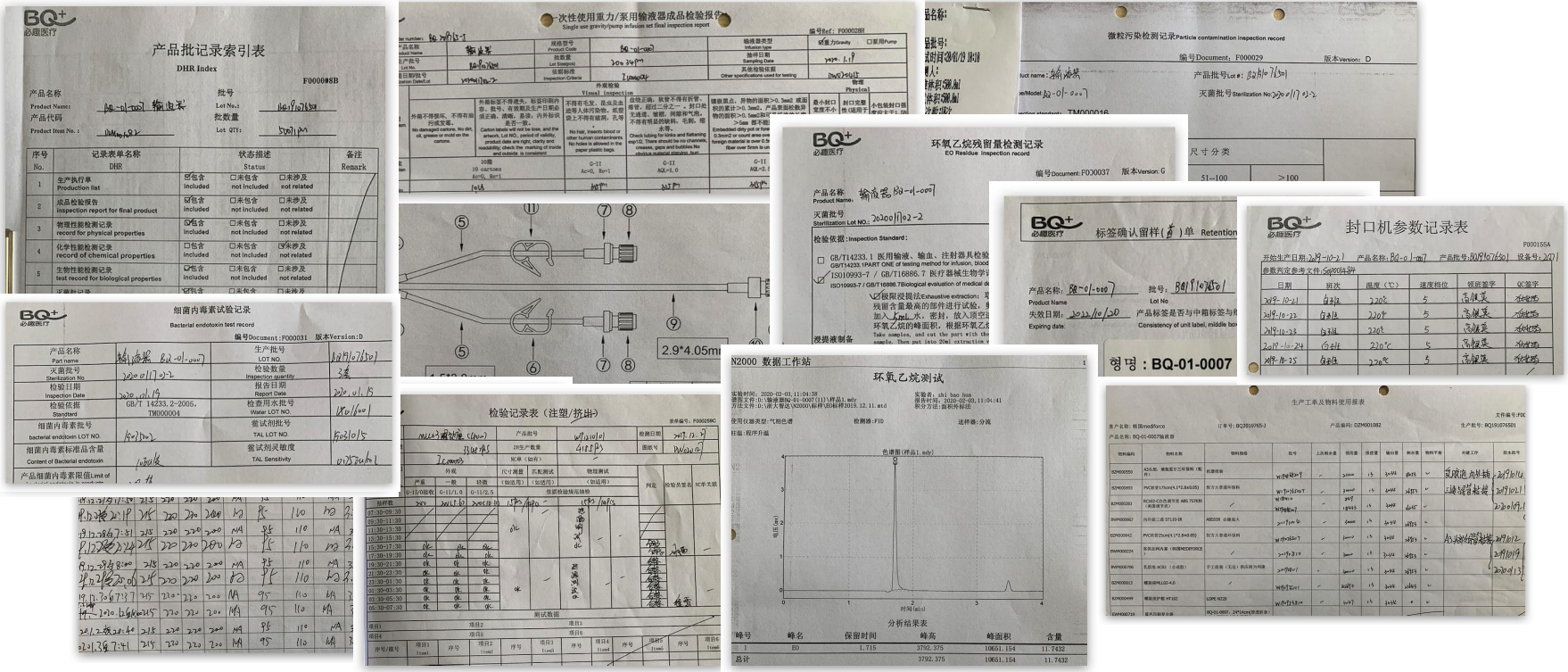
10. How does BQ+ ensure product traceability?

In the whole process of production, BQ identifies and records raw materials, semi-finished products and products to ensure that the product status and source of raw materials can be identified and traced from the whole process of material in-coming, production, inspection and delivery.
We have the order #, raw materials code & Lot #, product code, lot #, quantity, production/test equipment, equipment operation parameters, sterilization lot #, sterilization parameters, test results, disposal of non-conforming product information such as records, and confirmed by the corresponding management personnel, ensure record fill in accurately and timely.
After the production of a certain batch of products is completed, all production and inspection records shall be uniformly filed into the batch records of that batch, which shall be checked by the personnel of the quality department and then filed to the document control department of BQ company for safekeeping.
After the delivery of products, if there are any abnormalities or complaints, we can trace the product code, batch number and other information back to the batch records, repeat the production process, and investigate and analyze the causes of abnormalities.

Next page: Batch records examples…

10. How does BQ+ ensure product traceability?

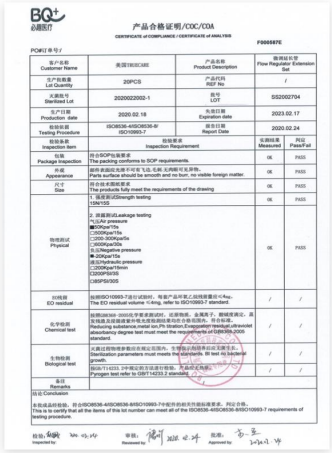
BQ+ batch records examples:



11. How do I know the order status and quality level before shipment?

BQ+ sales team is base in factory, and they keep interaction with production, quality and logistic team. They are following your order status and quality controlling, in case there is any issue, you will know it immediately.
BQ+ sales representative will send you photos/videos to keep you posted.

FQC will be done before releasing goods from BQ+ factory, COC/COA will be issued by BQ+ laboratory. You could do “remote video inspection before shipment” and see container loading through sales representative’s mobile phone camera.



产品合格证明/COC/COA

上海必趣医疗科技有限公司

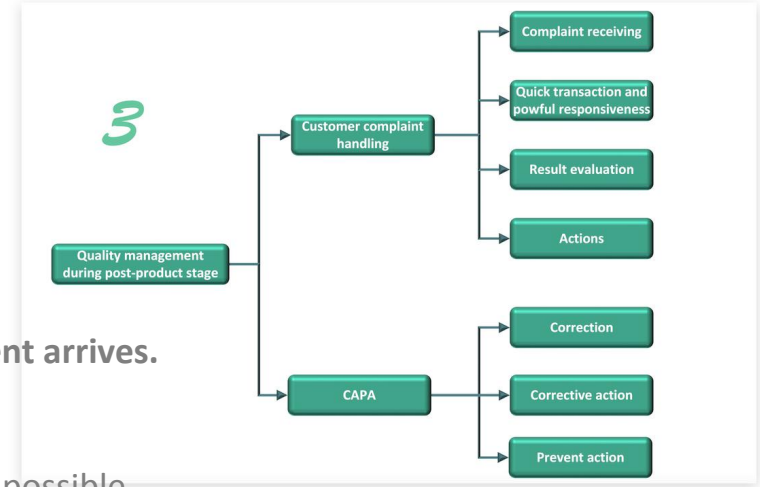
EO-Sterilization Record Per Load

环氧乙烷灭菌批记录

12. What if there quality issues after I received the shipment?

Don’t worry, BQ+ guarantees

- ✓ Sales responds in 24 hours
- ✓ Investigation in 3 days
- ✓ Proposal of Solution in 7 days
- ✓ CAPA close in 30 days



The following support needed from your side:

1. **Please do inspections within 30 days after shipment arrives.**
2. **If there is any quality issue,**

- ➢ It is helpful to provide photos or videos.
- ➢ Please describe the scenario as detailed as possible.
- ➢ Please provide your inspection result, test method and sampling standard.
- ➢ Please let us know the current disposition status of the problem products.

Consider BQ+ your reliable partner in China

BQ+ understands that your needs go beyond just purchasing medical device. Our engineers and technicians are very much experienced in medical device R&D, manufacturing and related regulatory compliance and government requirements. Working with BQ+ can reduce engineering, mold and equipment costs, as well as speed up your time to market.

If you don't find items from BQ+ catalogue that exactly fits your application needs, our sales representatives and product development engineers will work closely with you to solve your most challenging problems. We are committed to helping you achieve the best economics and performance from your products and will assist you in meeting relevant certifications and government regulatory requirements.

Many thanks & Best regards
BQ+ team

Thank you!