TÜVRheinland®

Audit Report

for

Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd.

1. Yucai Road, Beishe Town, Wujiang City, Jiangsu Province 215214, P.R.China

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1. Data and Summary

Holder of certificate/ approval	**Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd.** 1. Yucai Road, Beishe Town, Wujiang City, Jiangsu Province 215214, P.R.China
DIMDI code	**N/A**
Place of audit	**1. Yucai Road, Beishe Town, Wujiang City, Jiangsu Province 215214, P.R.China**
Auditee's Representative	**Ms. NI Aimei**
Order Number	**153076339**
Directive	[x] **Medical Device Directive 93/42/EEC, Annex V** [ ] **Active Implantable Medical Devices 90/385/EEC, Annex** [ ] **In Vitro Diagnostic Medical Devices 98/79/EC, Annex no.**
Standards applied*	[x] **EN ISO 9001:2000** [x] **EN ISO 13485:2003** [ ] **ISO 13485:2003 under CMDCAS**
Regulation	[ ] **MHLW Ministerial Ordinance No. 169, 2004**
Miscellaneous	[ ] **TCP (Technical Cooperation Programme between EU AIMD/MDD/IVD Notified Body Partners and DOH Designated Auditing Organization) Taiwan**
Type of Audit**	[ ] **Pre-Audit** [x] **3rd Surveillance and Extension** [ ] **Certification/Registration** [x] **1st Surveillance audit for CMDR** [ ] **Repeat** [ ] **Extension/Upgrade Audit**
Date of Audit	**5/10/2007**
Lead Auditor	**Ms. REN Xiaoli**
Auditor(s)	**Mr. FAN Tao, Mr. Daniel ZHU (Trainee)**
Translator	**N/A**
Language of audit	**Chinese**

*Fields may be modified.
**For CMDCAS Certification Audit the term Registration Audit should be used.

Within the scope of the audit, the company has furnished proof that it maintains a quality system in accordance with the above-mentioned EN ISO 9001:2000, EN ISO 13485:2003, ISO 13485:2003 Effective Implementation of Part 1, CMDR, MDD 93/42/EEC Annex V and that the requirements are fulfilled.
Therefore, it is recommended that a TÜV Rheinland Product Safety GmbH Notified Body (0197) approval (DD), as well as a TÜV Rheinland Product Safety GmbH quality system certificate (SY) should be issued.

Additionally, it is recommended that the TÜV Rheinland of North America, Inc. quality system certificate according to ISO 13485:2003 under CMDCAS should remain valid.

The company made substantial changes to the product range during the surveillance period. It is recommended to extend the scope of the approval/certificate for the above-mentioned products. (see section 3.2)

The following pages contain more detailed information about the audit.

2007, 06, 01
Date

Lead Auditor

Auditor(s)

2. Objectives and basis of the audit

TÜV Rheinland Product Safety GmbH and TÜV Rheinland of N.A., Inc. were contracted by Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd. to perform a 1st Surveillance Audit for CMDR, 3rd Surveillance and Extension Audit.

The basis of the audit was as follows:

- MDD 93/42/EEC Annex V
- EN ISO 9001:2000, EN ISO 13485:2003, ISO 13485:2003 Effective Implementation of Part 1, CMDR
- ISO 13485:2003 under CMDCAS. Evaluation of the effective implementation of all appropriate provisions of Part 1 of the Canadian Medical Devices Regulations into the Quality System
- Quality assurance manual (QA manual),
- Procedures, work- and test instructions valid at the date of the audit.
- Applicable Standards:

EN 550:1994	EN ISO 14698-1:2003
ISO 11135:1994	EN ISO 14698-2:2003
EN 556-1:2001/AC:2006	EN ISO 11138-1:2006
EN ISO 14971:2000+A1:2003	EN ISO 11138-2:2006
EN 980:2003	EN ISO 10993-1:2003
EN 1041:1998	EN ISO 10993-4:2002/A1:2006
EN ISO 11607-1:2006	EN ISO 10993-5:1999
EN ISO 11607-2:2006	EN ISO 10993-7:1995
EN ISO 11737-1:2006	EN ISO 10993-10:2002/A1:2006
EN ISO 7153-1:2000 (Stainless steel)	

The purpose of the audit was to verify that the above-mentioned requirements were fulfilled.

Changes to the approved quality system documentation were reviewed prior to the 1st Surveillance Audit for CMDR, 3rd Surveillance and Extension Audit and found to be acceptable.

The designated Authorized European Representative is:
Chinese Medical Center, BV Amsterdam
Geldersekade 67-73 1011EK, Amsterdam, The Netherlands

The responsibilities are defined in a contract between the company and its Authorized European Representative. The processes and interfaces are described in the respective documents.

3. Scope

3.1 General

The TRPS quality management system certificate of Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd. based on EN ISO 9001:2000, EN ISO 13485:2003 shall be related to Manufacturing and Distribution of Disposable Blood Lancets, Disposable Acupuncture Needles, Disposable Dermal Needles, Disposable Press Needles, Disposable Tattoo Needles, Disposable Ear Needles, Disposable Intradermal Embedding Needles, Dermal Rolling.
The Notified Body approval shall be related to Manufacturing and Distribution of Disposable Blood Lancets, Disposable Acupuncture Needles, Disposable Dermal Needles, Disposable Press Needles, Disposable Tattoo Needles, Disposable Ear Needles, Disposable Intradermal Embedding Needles, Dermal Rolling.

The ISO 13485:2003 certificate under CMDCAS is related to Manufacturing and Distribution of Disposable Blood Lancets, Disposable Acupuncture Needles, Disposable Dermal Needles, Disposable Press Needles, Disposable Tattoo Needles, Disposable Ear Needles, Disposable Intradermal Embedding Needles,

Currently, approximately 19 employees are employed at Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd., working on 1 shift.

The audited areas/departments and their processes, as well as the audited personnel, are identified in the attached audit plan.

Exclusions / Non-applicability: 7.3, 7.5.4 / 7.5.1.2.2, 7.5.1.2.3, 7.5.3.2.2 and 8.2.4.2.

Multi-site certification: N/A

3.2 Changes since the previous audit

The organization has extended one product, Derma Rolling, which is one kind of acupuncture needle with similar production & inspection process and similar raw materials. The product relative documents has updated and cooperated into the QM system, e.g. the opera-

tion WIs, the inspection WIs, the CE technical file, YL/CE-001. The organization has registered the product in SFDA of China.

The organization QMS has no other changes except what mentioned above, e.g. organization structure no change; European Representative no change; the Canada market is stable, e.g. the DISPOSABLE STERILE ACUPUNCTURE NEEDLES, device licence, No. 73871, has no change; the production and inspection process for previous products has no change and the maximum production capacity has no change; the top management has no change and the employee is stable, e.g. the management representative is still Ms. Ni Aimei.

The USA FDA will audit the organization on site in next month, and the organization has already made fully preparation.

There is no deviation in last surveillance audit.

3.3 Outsourced processes

For outsourced processes, e.g. electroplating process, the manufacturer has demonstrated proper control over the subcontractor(s) (e.g. incoming inspection).

4. Audit process and findings

4.1 Audit process

Within the scope of the audit, processes in the various departments of Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd. have been audited in order to verify conformity with the requirements of the above-mentioned directive, standards and descriptions in the quality management system documentation. This verification was performed on a sampling basis, by interviews, review of the corresponding documentation and observation of processes.

The following QM system requirements were covered during the audit:

- Identification of processes, their sequence and interactions, and the measuring and monitoring of processes (4.1, 8.2.3.)

The company's existing processes were identified and specified. The sequence and interaction of the processes was illustrated clearly. The essentials of the established quality system have been discussed with the appointed Management Representative. The quality manual, procedures, necessary work instructions and specifications was made comply with the standards requirements.

- Documentation requirements (4.2)

Quality manual, YL/QM001 Rev. C, issued dated 2005-03-28 remains no change since the previous audit.

Procedure for document and record control is defined in YL/QP012 and YL/QP013. Distribution scope has been identified and recorded in QP012-06 from which the controlled documents in specified personnel could be checked. The issue and receipt of controlled documents are recorded in distribution registration record (no. QP01201).

External document list was established including external standards and regulations etc and found to be acceptable.

- Management responsibility, management review, quality objectives (5)

The company's implementation of the standard, for which the management representative, is responsible, essentially corresponds to the requirements of EN ISO 9001:2000 and EN ISO 13485, CMDCAS ISO 13485:2003, and MDD Directive 93/42/EEC Annex V, in terms of both documentation and practical implementation.

Company management has declared that as of its quality policy is binding, and has implemented this policy.

The quality policy is suitable and creates a framework for the respective quality objectives. It obligates all personnel to continually improve the QM system. (List main content points)

The procedures and responsibility are defined in the SOP YL/QP001, The management reviews were conducted once last year. And the latest management review is performed on Dec 25, 2006. The management review frequency could be increased adequately for there is one product extended in the QMS. Records of these reviews were maintained. Especially the evaluation of the QM system in regard to the requirements of the Directive 93/42/EEC Annex V, CMDCAS ISO 13485:2003, and the applicable standard EN ISO 13485 is performed.

The agenda of annual review included the annually analysis report from sub departments, Statutory requirement update, quality objectives review, internal audit, CAPA, customer satisfaction, product of non-conformance, suitability and effectiveness of quality system and statistic from internal audit. The 9 items were discussed; also quality objectives are reviewed in the management review. The target data annual was completed in the fiscal year evaluation. The new action is defined after the reviewing

- Human resources (training) (6.2)

Training procedure is regulated in YL/QP004. Supporting documents for implementation of trainings have been established, e.g. job training requirement (WI-T-02), job qualification requirements (WI-T-04) and tutor qualification requirements (WI-T-06). The trainings records were checked based on sampling method and found sufficient, e.g. staff training files of sterilizer operator CHEN Gang and PQC inspector TANG Meifang.

Annual training schedule of 2007 has been established according to Training Request Sheet (QP005-01) and approved dated 2006-12-26. Training of production operation skills were conducted based on work instruction WI-T-20 & WI-T-21 as planned on Mar 2007. QC inspector skills training was scheduled and accomplished as well. The training records were checked.

- Infrastructure (6.3)

Control of infrastructure, especially for the production equipment, is performed in accordance with YL/QP007. Equipment list (QP007-01), equipment annual maintenance schedule (QP007-04), equipment maintenance records (QP007-05) were checked and deem sufficient. For important equipment, e.g. heat-sealing packaging machine and EO sterilizer, to ensure normal running of the production, daily check is conducted and recorded in equip-

ment daily maintenance record (no. QP007-03). The recent annual maintenance EO sterilizer was conducted on 2006-12-12, and next annual maintenance has been scheduled.

- Work environment (6.4)

10^5 class cleanroom was provided for the manufacturing of sterile products. The workshop was controlled according to ISO 14644-1/2 and inspected by QA department. The cleanroom was monitored by Jiangsu Medicine Inspection Institute annually, e.g. report No. 2006J0233, dated on 2006. Nov. 27. 10^4 class cleanroom was provided for Quality Department for microbiological tests, and the clean room was also monitored by Medicine Inspection Institute annually, e.g. report No. 2006J0234, dated on 2006. Nov. 27 and by Quality department according to ISO 14644/ YY 0033.

The monitoring of the cleanroom is conducted based on the specified frequencies, such as airborne particles, pressure difference, airflow, temperature, humidity and charged by quality department. Corresponding monitoring records were checked on site and deemed to be acceptable

- Customer-related process (7.2)

Procedure for customer-related process is defined in DP no. YL/QP002. Quotations mainly come from oral communication via telephones. Oral orders record (QP03-01-01) would be then converted into Contract Review Form (QP002-02) for review of production department, sales department and GM. After approval, contract would be signed with customers, Production Notice of Sales Contract (QP09-01-01) issued to production department. Sales Department is responsible for monitoring the accomplishment of each contract till the delivery of product. The sales and delivery records of acupuncture needles (order no. OR-07005) were checked and found acceptable.

- Purchasing (7.4)

Approved supplier list, approved dated 2007-01-01, was checked, including suppliers of raw material, bio-indicator, and equipment. Agreement with subcontractor of outsourced process e.g. electroplating process includes the content of incoming inspection specification and packaging requirements. Technical agreement with stainless steel wire supplier was checked as well, which regulates the detailed specifications including material, wire diameter etc.

Purchasing flowchart and procedure are clearly defined in DP no. YL/QP005. Purchasing order would be issued to the approved suppliers according to sales order and follow-up purchasing plan.

Evaluation of supplier is the responsibility of Purchasing Department. The factors, e.g. conforming rate, customer complaint, service etc, are considered and evaluated once a year. On-site visit to several suppliers of raw materials was conducted during Dec 2006, Supplier Survey Sheet (QP005-01) was established, e.g. for stainless needle supplier.

- Production and service provision incl. (7.5, 6.4)

Production is organized in a way that the Work order is converted from confirmed sales order; the production start from subcontracted activity for un-platted needle, subjected to in house 1st QC inspection; subcontracted again for plate and cleaning, 2nd QC inspection; the

in house production start from this point on, which means cleaning and assembly, blister/paper package, and subject to ETO sterilization. Example has been checked for order OR07001, 0.20mmX25mm, lot size 100 thousand pcs, sliver platted as handle.

The blister/paper package process is considered as special process, and process parameter is controlled for sealing temperature and time. The sealing integrity is checked by ink-dye method.

- Validation activities (7.5.2)

ETO sterilization, while conditioning in the same chamber as sterilization, is performed at WUJIANG Cloud & Dragon, on annual basis. The validation has been performed in Cloud &Dragon by 2006. 12.18, including the new type of acupuncture needle which to be extended during this audit. The validation is performed with half cycle method, with 22 bio-indicators, of ACTT9373 population $1.5x10^6$ cfu/piece, and physical parameter at 50 degree, 50%RH, 650 mg/L, holding time 240min (half cycle, and full cycle 480min). The temperature profile has been checked by 11 temp. sensors and found compliance, for sterilizer type HDX 6 m^3, which is provide by Hangzhou Dianda.

The EO residual was evaluated according to EN ISO 10993-7, find compliance 10ug/piece. The bioburden evaluation is performed per batch, e.g. once a month e.g. dated 2007/ 04/ 11,4cfu/set.

The heat sealing process validation is performed in Dec. 2006, the report is in number JC-06001. The temperature range (120-130 °C) and sealing time (2 second) are defined in the revalidation. Routine control is monitored in the light to validation report. Now the blister pouch is used in the primary package. The package material specification is defined and incoming inspection is performed in the QC dept.

- Control of monitoring and measuring devices (7.6)

The control of monitoring and measuring devices is charged by quality department. The lab. of QA department is checked, e.g. the physical features inspection lab, microbiological features inspection lab, and sampling products maintain room. The calibration plan is made once per institute of Measurement and Testing Technology, CNAL No. L1861 according to calibration plan, and the detail certificates for sampled devices are checked, e.g. for micrometer, Cert No. 20060101104205; for needle sharpness test machine, Cert. 20060181104018; for steel rigid test machine, Cert. 20060181104016

- Monitoring and measurement of product (8.2.4)

For each product batch, the whole DHR are collected and maintained in one binder. From acupuncture needle maintain history list, batch 07003, 07004 were sampled to check the whole inspection process and the maintained DHR, e.g. for production Lot. 07003, sterilization Lot. 07003S, production notice form, QP09-01-01, dated on 2007. Mar. 1; final product physical features inspection report, QP010-04, No. 07003-01, dated on 2007. Mar. 23, production process inspection records QP10-02-02, No. 02 (according to key process inspection procedure, WI-Q-14), sterile test report, No.003 dated on 2007.Mar. 21 (including product sterile test and BI sterile test, 11 BIs used for routine monitoring), and final product inspection report according to National standard, GB2024-94, QP010-05, No. 003, dated on 2007. Mar. 27, product in-stock form, were maintained in one binder and checked and deemed to

be acceptable. According to the material acceptation sheet in DHR, the used main material can be traced and corresponding inspection report were checked and deemed to be acceptable, e.g. the used dialysis paper used Lot. D-07001.

For extended acupuncture needle type, Dermal rolling, the updated WIs were checked and deemed to be acceptable, e.g. the production process flow chart, WI-T-33, the rolling inspection criteria, WI-Q-25, assembling WI, WI-T-33, final product inspection criteria, WI-Q-31. The corresponding inspection reports/ records were checked and deemed to be acceptable, e.g. the final product inspection report, QP019-03, No. 070110, dated on 2007. Jan, 12 for Dermal Rolling, Lot 070110.

The product bio-burden evaluation is performed per batch, e.g. for acupuncture needle Lot. 07003, test report No. 003, dated on 2007. Mar. 20 according to WI, WI-T-19, the average inspection result is below 5 cfu/needle.

- Customer satisfaction/customer feedback (incl. complaint handling), vigilance system (8.2.1, 8.5)

Measurement of customer satisfaction: YL/QP016.

Inquisition forms of customer satisfaction (no. QP016-04) would be filled based on survey on several main customer. Analysis report would be established based on the information from the inquisition forms. These records were checked onsite and found acceptable. The results show that the customers are satisfied with the products and service.

No complaints have received and no vigilance & recall cases happened since the previous audit.

The post market surveillance ensures, that incidents/recalls related to products, which are sold in Canada are reported to the Minister of Health.

- Internal audits (8.2.2)

The internal audit was performed once last year and the records of last audit implemented during 2006-12-18 to 2006-12-19 were reviewed in detail. All QM elements were covered and the records of audit plan, QP017-02, No. SL/06-01, audit questionnaire, QP017-03, and audit result was available. Ms. Ni Aimei and Ms Zhou Xiaozhen performed the audit and established two deviations. The audit result deemed that the QM system was effective. CAPA was performed and closed the deviations in time.

- Corrective and preventive actions (8.5)

The CAPA procedure is defined in the document no. YL/QP014 and YL/QP015. Most CAPA come from audit results and management review. At the moment there are no reportable vigilance cases, recalls to be happened since last audit.

- Risk management (7.1)

The risk evaluation has been performed, and confirmed that no new risk been identified, since no adverse aspect of the market feedback, no production process change and no new awareness of any technical development in the relevant field.

The biocompatibility evaluation is done by the material composition of the stainless steel wire, 0Cr19Ni9, The certificate of analysis from qualified supplier is demonstrated to conform with the specification of stainless steel wire. For extended Dermal Rolling, the same steel wire is used and the biocompatibility is also deemed to be acceptable.

- CMDCAS: The device license(s) held by Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd. was reviewed and confirmed under the name of the legal manufacturer. Devices that are being sold/intend to be sold into Canada have been audited.

- Technical documentation

Technical documentation was reviewed on a sampling basis for compliance to the requirements of Directive 93/42/EEC, Annex V for Disposable Blood Lancet, Disposable Acupuncture Needle, Disposable Dermal Needle, Disposable Press Needles, Disposable Tattoo needles, Disposable Ear Needles, Disposable Intradermal Embedding Needles, Dermal Rolling The technical file, YL/CE-002 Ver B (for Blood Lancet), YL/CE-001 Ver B (for acupuncture kind of products), has been updated due to some new European norm was updated, issued dated on Jan 2007, YL/CE-001 Ver B is also updated for the extended acupuncture needle type, Dermal Rolling.

The following items were reviewed in detail:

- Product Description (YL/CE-001-01, Rev.B)
- Classification of the products, including intended use and rule (YL/CE-001-01, Rev.B)
- Essential Requirements Checklists (YL/CE-001-012 Rev.B)
- Risk Management (YL/CE-001-03, Rev.B)
- Product manufacturing procedure (YL/CE-001-04, Rev.B)
- Labelling and packaging (YL/CE-001-08, Rev.B)
- Declaration of Conformance (YL/CE-001-10, Rev.B)
- List of applied product/performance standards (YL/CE-001-10, Rev.B)
- Clinical evaluation (YL/CE-001-06, Rev.B)

4.2 Findings

During the audit, no deviation has been established.

5. Conclusion

Wujiang City Cloud & Dragon Medical Device Co., Ltd. / Wujiang City Shen Ling Medical Device Co., Ltd. has furnished proof that it maintains a quality management system that fulfils the above-mentioned requirements.

The Quality manual contains descriptions of all processes. Also the interactions of processes are identified and described. Methods for the measurements of customer satisfaction are defined and implemented.

Documented procedures which are required by the harmonized standard EN ISO 13485:2003 are described in the QA documentation.

The requirements of ISO 13485:2003 under CMDCAS were fulfilled. The manufacturer has documented and effectively implemented all appropriate provisions of Part 1 of the Canadian Medical Devices Regulations into their Quality System.

Within the scope of the quality management system, all applicable QMS requirements have been described in sufficient detail in the quality manual, procedures and instructions. The quality management system requirements 7.3, 7.5.1.2.2, 7.5.1.2.3, 7.5.3.2.2, 7.5.4 and 8.2.4.2 were not applicable.

During the audit, the auditors verified that processes were performed in accordance with the quality management system documentation.

The technical documentation, as reviewed, was deemed to be in compliance with the applicable requirements.

Management documented its commitment to implement and maintain the quality system by approval of the quality manual. The quality policy and the defined quality objectives were disseminated through all levels of the organization. The company implemented and maintained procedures and processes to achieve defined quality objectives. Personnel on all levels of the organization had the necessary awareness of the quality management system.

The responsibility and authority of personnel who manage, perform and verify work that affects the quality of the products were defined.

Resources for maintaining the quality management system were sufficiently provided by the management.

Procedures describing responsibilities for identifying failures and non-conformities were implemented. Review of the effectiveness of corrective and preventive actions was performed by the manufacturer.

Internal audits were planned and performed to guarantee the maintenance and a continual improvement of the quality management system. The internal audit program ensured that findings during internal audits were followed up in a timely manner.

Procedures describing responsibilities for identifying failures and non-conformities were implemented. Resulting corrective and preventive actions were followed up.

The post market surveillance procedures and the implementation of the resulting corrective and preventive actions were evaluated and found to be effective.

6. Observations

The audit team would like to point out the following observations:

- The updated standards could be better evaluated in management review.
- The management review frequency could be increased adequately for there is one product extended in the QMS.

- The internal audit schedule could also include the requirements of 21 CFR 820.
- The main material IQC test report could be also collected in the binder of corresponding product Batch DHRs.

7. General notes

TÜV Rheinland Product Safety GmbH requests to be notified in case of any significant changes to the company's quality management system (e.g. changes to procedures which concern the development, the production or the end control) during the time of validity of the certificate. Furthermore, TÜV Rheinland Product Safety GmbH requests to be notified in case of product recalls for medical or technical reasons as well as for any report on incidents or near incidents as defined in the current version of MEDDEV 2.12/1 (Guidelines on a Medical Devices Vigilance System).

TUV Rheinland of North America, Inc. requests to be notified in case of any significant changes to the company's quality management system (e.g. changes to procedures which concern the development, the production or the end control) during the time of validity of the certificate. Furthermore, TUV Rheinland of North America, Inc. requests to be notified in case of product recalls for medical or technical reasons as well as for any report on incidents or near incidents as defined in the Canadian Medical Devices Regulations.

The audit was performed by means of sampling objective evidence. Therefore, further deviations not established during the audit may exist. The findings and conclusions of the auditors do not release the company from its responsibility to ensure compliance with and constant observance of the requirements of the applicable standards.

End of Report

8. Attachments

Audit plan