PROQC
INTERNATIONAL
Global Quality Control and Engineering Solutions

GMP Audit Report

** Example Report **

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	SUMMARY	0

Supplier Name	Audit Date	Report No.
xxx	xx-xx-xxxx	xxx

SUPPLIER'S INFORMATION		CLIENT'S INFORMATION	
NAME :		NAME :	
ADDRESS :		ADDRESS :	
CITY :		CITY :	
COUNTRY :		COUNTRY :	
PHONE :		PHONE :	
FAX :		FAX :	

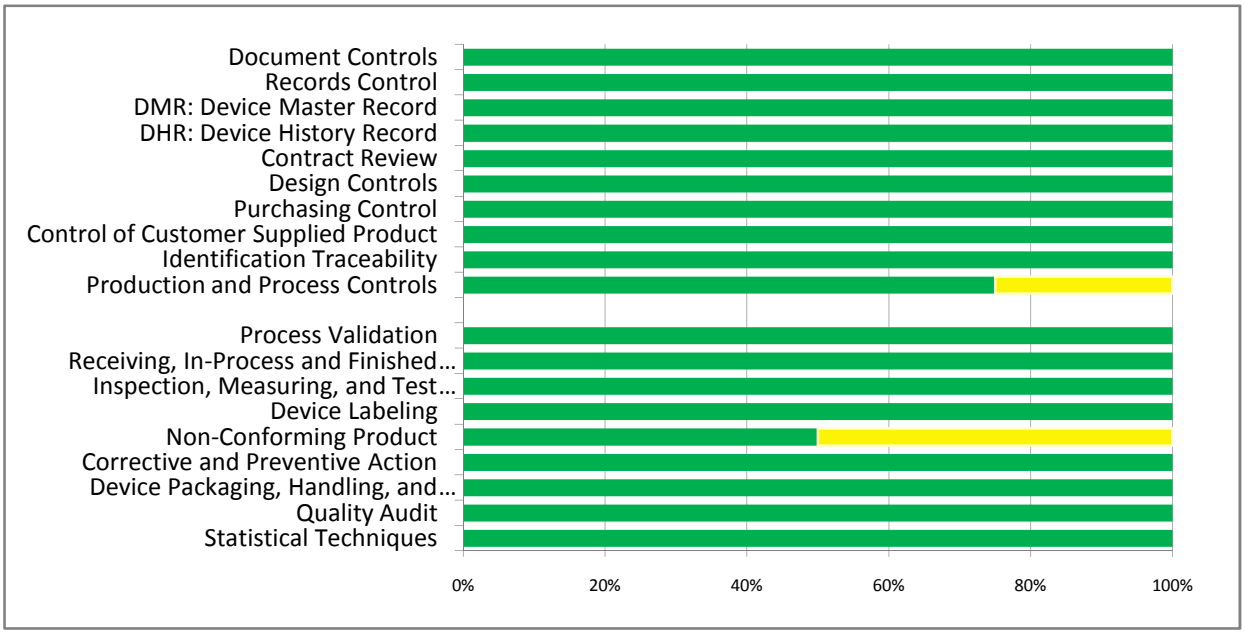
SUPPLIER'S PERSONNEL PARTICIPATING

Mr./Mrs.		Title:		Email:	
Mr./Mrs.		Title:		Email:	
Mr./Mrs.		Title:		Email:	
Mr./Mrs.		Title:		Email:	

Pro QC PERSONNEL

Mr./Mrs.		Title:	
Mr./Mrs.		Title:	

AUDIT RESULTS



JUDGMENT & RECOMMENDATIONS

- ☐ **Passed - T**he QMS is effective; you could use this supplier as a reliable business partner.
- ☑ **Passed - T**he QMS is acceptable with minor ncf (see **Audit Report**); you could use this supplier as a reliable business partner, but keep pushing them for improvement to reduce risk.
- ☐ **On-Hold** - The QMS presents few major ncf (see **Audit Report**); you could request them to provide a CAPA before you engage in any business.
- ☐ **Failed - T**he QMS presents serious major ncf (see **Audit Report**) that could impact your your business. The better solution is to source from another supplier.

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Scope of Audit:

The intent of conducting a quality system audit based on QSR 820 requirements is to provide the client with information useful for making an initial assessment regarding business viability and reducing their sourcing risks.

Summary/Recommendation:

The audited factory has XX production sites on a total land of XXXXXXX square meters. Production areas are distributed among XX different workshops / buildings, including a 100000 Class Room of XXXXX square meters at the workshop A11 where the product XXXXXXXXXX will be produced.

The factories also have a ETO Sterilization Chamber under a different business license. XXX% of product to USA market is sterilized here. Products are sent to those chambers under a sub-contract external service. The audited factory maintains record of process validation of those chambers, including production record linked to DHR files.

The factory has ~XXX workers, but with around X or less focused in the production of XXXXXXX. The factory is certified to ISO 13485 and CE, Registered to FDA and compliant to GMP.

DMR files are maintained for project developed and fully compliant to the requirement of 820.181.

DHR files are maintained per lot produced, with all records of IQC, IPQC, FQC both in product are process, training of operators, environmental check…etc, fully compliant to 820.184.

Traceability in product and related records is reliable, even that it is manually controlled. However, the factory should make more effort to ensure the space limitation in the last step of packaging to avoid not affecting proper identification and traceability of packaging boxes.

We also recommended the factory maintain a cleanliness schedule visible on-site on a daily basis. Same recommendation will apply to the environmental check plan and record.

Strengths:

1) Certified to ISO 13485, CE, registered to FDA with quality management fully documented.
2) Have a dedicated personnel to ensure conformity to requirements related to medical devices.
3) Very large manufacturing center with 11 workshops in the same place.

Opportunities for Improvement:

1) Should manage sufficient space at the packaging area to ensure proper position and identification of packaging material.
2) Should keep a record of cleanliness, as well as record of environment control up-to-date and readily available on site, with the purpose to enhance employees in their effort to ensure compliance in this aspect.

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	QUESTIONNAIRES / EVIDENCES	FINDINGS	SCORE
1	**Quality System (ISO 4.1, 4.2, 5.1, 5.3, 5.5 / QSR 820.5, 820.20)**		
1.1	Is there evidence that the quality policy is understood by all personnel? Public posted, record of training, etc.	The quality policy is written in page 23 of Quality Manual (XXXXXXX) which was approved and published in xxxx-04-11. In addition to regular training, the same content of the quality policy is posted at various place of workshop, including in the employee ID card.	C
1.2	Is an organizational chart documented and accurate?	Yes, the organization chart is accurate and documented in the 13th page of the Quality Manual (XXXXXXX). See photo #8.	C
1.3	Are responsibility & authorities defined?	Yes, responsibilities / authorities are detailed in the 17th page of Quality Manual (XXXXXXX), See photo #9.	C
1.4	Is there a person nominated as Management Representative? Is the nomination in written and approved by company authorities?	Mr. **XXXXXXX** is nominated as Management Representative since xxxx, with nomination letter attached to Quality Manual in page 4. See photo #10.	C
1.5	Is a Management Review conducted on regular basis? Are records of the last management meeting available?	The management review is conducted following the procedure (XXXXXXX), record of last management review meeting conducted in Jan 15th , xxxx are available as following: - Management review plan in form XXXXXXX - Record of opening meeting in form XXXXXXX - Report of management review in XXXXXXX	C
1.6	Are required Quality System procedures developed and up-to-date?	Yes, the factory has developed 41 procedures as guidance to compliant to requirements of ISO 13484, FDA 21 CFR 820, MDR etc. Theses procedures are listed in the annex of page 58 and 59 of the Quality Manual. See photo #6.	C
2	**Personnel (ISO 6.2.2 / QSR 820.25)**		
2.1	Are training needs identified, planned and completed? Are traning records available?	Yes, training is conducted according to the procedure (XXXXXXX). Training plan of year xxxx is documented. See photo #11. It includes few training records been implemented saved in the sheet# XXXXXXX. For example, training code # XXXXXXX conducted in xxxx-06-15 about requirement of ISO 13485 / YY0287 / QSR 820. See photo #12.	C
2.2	Do qualified people who need a CV have one?	All Internal Auditors have CV, including people working on site.	C
3	**Document Controls (ISO 4.2.3 / QSR 820.40)**		
3.1	Is there a system or procedure to organize the edit, update, revision, distribution of quality system documents?	Yes, documents are controlled according to the procedure (XXXXXXX).	C

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3.2	Are up-to-date or current revisions of SOP's and data sheets used on site?.	Any change in documents are required to be applied in form (XXXXXXX) with record of others documents to be affected by the change, then submit to the original person who created the document for approval. See photo #13.	C
3.3	Is there a Master list of document under control showing change status?	The factory maintains up-to-date a master list of all documents, including title, doc# and status of current revision.	C
3.4	SOP's are up-to-date? Cross check with SOP on site.	Reviewed onsite work instruction at the Injection process: - Work Instruction (XXXXXXX) on machine ##### - Work Instruction (XXXXXXX)	C
3.5	Are technicians familiar with the SOPs that affect quality?	Operators are familiar with SOPs.	C
4	**Records Control (ISO 4.2.4 / QSR 820.180)**		
4.1	Are records stored properly?	Yes, records are controlled according to the procedure ((XXXXXXX).	C
4.2	Is restricted access practiced?	Production record is saved to the central place per each PO, together with all DHR files involved. The central place is maintained by the responsible of compliance.	C
4.3	Check log books, notebooks, folders and data sheets for proper documentation practices (cross-outs, writeovers, white-out, etc.).	Records are properly identified, with folders, cross-outs etc to facilitate the quick finding when needed. During the audit, it only takse them around 1 to 2mns to get the record the auditor needed.	C
5	**DMR: Device Master Record (QSR 820.181)**		
5.1	Are device specifications included in the DMR?	Yes, device specification are documented in the file #######, see photo#14. It includes: - Product drawing ####### - Packaging list and requirements - Label printing requirement for small / external carton box. - Manual printing	C
5.2	Are all SOP's for production in the DMR.	Yes, all SOPs for the production are documented in the file (XXXXXXX).	C
5.3	Are inspections, labels, and tags identified?	Yes, inspection instructions are defined in the file (XXXXXXX) . Label, tags requirements are documented in the file (XXXXXXX) . List of inspection equipment to use are listed in the file (XXXXXXX).	C

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5.4	Specifications for labeling?	Yes, specification for labeling is defined in the file (XXXXXXX) . Sterilization is conducted at external service, and have been identified as special process in the file manufacturing process flow chart (XXXXXXX).	C
6	**DHR: Device History Record (QSR 820.184)**		
6.1	Can you find the dates of processing?	Yes, can find the production date of the lots produced, all visible in all record of DHR of each lot.	C
6.2	How many were completed? How many were released?	The auditor found 3 lot numbers completed and released (######A, ######B and ######c). More specifically, the auditor reviewed the DHR of product model number #####3, Lot#0A, quantity 58708 pieces produced from PO# xxxxxxx of 58500 pieces planned from xx to xx.. It has following acceptance and rejection records. See photo #15. DHR summarized in the sheet (XXXXXXX) that list record of IQC, IPQC, PQC, FQC, samples and sterilization record. See photo #16.	C
6.3	Are acceptance and rejection records of incoming inspection available for the lot inspected?	Yes, summary of lot# of raw material, label, packaging material and related inspection PO# used for the production of product ####333 of general lot####33 in the sheet (XXXXXXX). See photo #18, including related record of incoming inspection.	C
6.4	Are acceptance and rejection records of In-process inspections both for product and process available for the lot inspected?	1) Yes, record of IPQC on component at Injection process on machine #KNS-209, KNS-001, KNS-009 in the day 2015-08-11/12, written in the sheet#QR-21-02-08, see photo #19. 2) Record of Injection process parameter on machine KNS-009, KNS-001 written in sheet #QR-12-ZS-01-B . 3) Record of welding process parameter of 2 components S4470/S4471 of part#CEB02 on machine KNS-012, KNS-013 in the day 2015-08-11/12, written in the sheet# QR-12-RH-01-B. 4) Record of IPQC at hot linking process, written in sheet # QR-21-24-01, conducted in day 2015-08-11/12 according to instruction #P2C-24A.	C
6.5	Are acceptance and rejection records of packaging process available for the lot inspected?	1) Record of packaging process parameter on machine######, written in the sheet (XXXXXXX) in the date to xxxx-08-13/14. 2) Record of IPQC of packaging process from machine KNS-031 written in the sheet (XXXXXXX) conducted in day xxxx-08-14.	C
6.6	Are acceptance and rejection records of final inspection available?	Record of FQC conducted according to Instruction #####33, written in sheet (XXXXXXX) , and written in the day 2015-08-14.	C

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6.7	Are records of cleanliness conducted during the product of the lot inspected available?	Record of cleanness of the day 2015-08-11/12 written in the sheet (XXXXXXX) .	C
6.8	Are records of the environment check conducted during the product of the lot inspected available?	Daily record of environment control of the workshop A4 of the month Aug during which the product ###### was produced between 2015-08-11 to 14, and written in the sheet (XXXXXXX) , see photo#20	C
6.9	Are acceptance and rejection records of the sterilization process, both product and process available?	Record of sterilization process by ETO following instruction (XXXXXXX) for lot######3 conducted in 2 separate sterilization lot # 15087257-4 and 15087259-4 for 585 cartons each lot., conducted in day 2015-08-15, See attached file.	C
6.10	Is labeling correctly identified?	Label is correctly identified. For example Ref.####33, Lot ####33A, Label lot# 2020-07 for product name , see photo #17.	C
7	**Contract Review (QSR 820.160)**		
7.1	Are there records that contract review is being performed?	Yes, contract review is conducted for each PO as required by the procedure APD-10, with result recorded in the sheet #QR-10-01B, see for example of client PO#xxx, converted to CONOD internal PO#xxxx, conducted in xxxx-6-24 under a cross function team that involved technical departments, quality, purchasing, production and sales representative.	C

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8	**Design Controls (ISO 7.3 / QSR 820.30)**		
8.1	Are following design history file available: a) Design input b) Design output makes reference to acceptance requirements c) Design outputs essential for the proper identification are identified d) Approval of design output	Design control is conducted as per procedure (XXXXXXX) . CONOD did not have any design responsibility on product EAR ULCER SYRINGE, since they receive drawing from client. The auditor reviewed an example of design control they did in a different product such as **XXXXXXX** in date xxxx-04-15, which is only design transfer project been developed with following sections: - Identification of need of design transfer. - The plan of design transfer. - Complement of design transfer. - Approval of design transfer. - Changes of design transfer. Input and output, including various stages of verification and validation of such design transfer were conducted and documented.	C
8.2	Are design review stages completed according to schedule?	Yes, all stage of design review were conducted, and with records having signature of the cross function in charge of the review.	C
8.3	Is design verification documented including: - Methods - Personnel	Yes, verification of design transfer are conducted according to planned method and evaluated by cross function of peoples listed in sheet (XXXXXXX)	C
8.4	Is design validation performed under defined operating conditions?	Yes, validation of design transfer is conducted according to planned.	C
8.5	Personnel and date of validation are documented?	Yes, personnel for the validation documented in the sheet (XXXXXXX)	C
8.6	Is design correctly translated into production specifications?	Yes, record of transfer to production are maintained	C
9	**Purchasing Controls (ISO 7.4 / QSR 820.50)**		
9.1	Is there a procedure for the control of purchasing operation?	Yes, the factory follows the procedure (XXXXXXX) to ensure conformity in purchasing process, including selection, evaluation and qualification of suppliers.	C
9.2	Are raw materials purchased from an approved vendors list?	Yes, the factory maintains a list of qualified suppliers from which they purchase raw material, including packaging elements. Records of Purchasing can confirm the origin of raw materials.	C
9.3	Are quality requirements on purchasing documents?	Yes, quality requirement to each supplier is documented and send to them.	C

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9.4	Are evaluation of suppliers, contractors, and consultants conducted as planned?	Initial investigation is conducted at supplier side with result recorded in the sheet (XXXXXXX) . The final evaluation is conducted in cross-function team and the result of such evaluation is recorded in the sheet (XXXXXXX) . Periodical supplier performance evaluation is conducted in monthly basis, with result recorded in sheet (XXXXXXX)	C
10	**Control of Customer Supplied Product (ISO 4.7)**		
10.1	Procedures that show control of verification, storage, and maintenance of Customer Supplied Product (CSP)?	The factory control customer supplier product following the procedure of (XXXXXXX) . Customer supplied product could be product directly sent by the customer to their factory, or by a raw materials supplier or sub-contractor selected and approved by the customer. The procedure also identifies methods for verification at incoming inspection, storage condition	C
10.2	Evidence that CSP which is damaged or is otherwise unsuitable for use is recorded and reported to the customer?	For the production of XXXXXXX, the factory used raw materials that come from the supplier/ or sub-contractor their selected and qualified. No evidence of CSP in this case.	N/A

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11	**Identification Traceability (QSR 820.60, 820.65)**		
11.1	Are all product (raw and test materials) are properly labeled or quarantined?	Product in the injection workshop is labeled as required in the procedure (XXXXXXX). See photo #25.	C
11.2	Look to see if test numbers, personnel, dates, Z #'s, are recorded on data sheets?	Label has information such as product name, lot number, date, and personnel. See photos #24, 25.	C
12	**Production and Process Controls (ISO 6.3, 6.4 / QSR 820.70)**		
12.1	Are all instructions formal?	Yes, work instruction are documented and visible on side, as it was defined in the DMR. See photo #26.	C
12.2	Revision #'s of controlled documents, labels, and signs?	The auditor has checked rev. of work instruction at molding injection workshop (XXXXXXX) stocked on machine #SB1800J6, and the document (XXXXXXX) . Each machine has its specific work instruction that include Injection standard parameter, detail of process flow, and inspection to conduct by the operator.	C
12.3	Processes are performed to their written procedures?	Yes, the process is performed as planned, for example of Injection, welding, packaging etc.	C
12.4	Check maintenance schedules.	Maintenance of production machine and installation are under responsibility of Technical Manager, as defined in the procedure (XXXXXXX). The maintenance plan is documented in the sheet (XXXXXXX), which was approved in xxxx-01-05. Record of maintenance is saved in the sheet (XXXXXXX) . The factory has around 35 equipments, including molding injection machines, tools, packaging machine, welding machine etc.	C
12.5	Validation of software processes.	The factory does not use specific software for the manufacturing of XXXXXX, except for software that are included in the injection machine, and in the sterilization process that is been sub-contracted to another organization. Proof of validation of such software is available.	N/A
12.6	Cleanliness schedule	Record of cleanliness are maintained in daily basis in another place, was not visible on site in the workshop, Record of cleanliness of the day 2015-08-11/12 written in the sheet (XXXXXXX)	I

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12.7	Environmental control	The procedure (XXXXXXX) provides guidance of how to maintain working environment in good condition. The Auditor did not see a written / visible housekeeping schedule on site. But record was showed as they are maintained in document center place. Temperature, humidity and inner pressure etc is checked every day of the production.	I
12.8	Contamination control	Access to the production area is limited to specific person with password in the entrance door. Method of wearing work clothes are documented with image in the wall as to display how to be clothed before enter in the premise. See photo #27.	C
12.9	Personnel health control	Every employee working in the premise has conducted adequate health check, and certificate was providing by legal hospital.	C
13	**Installation (ISO 4.9 / QSR 820.170)**		
13.1	If necessary, are there procedures for installation?	The installation process is not applicable for the audited factory.	N/A
13.2	Inspection of installation?	Idem	N/A
13.3	Installed by qualified personnel?	Idem	N/A

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14	**Process Validation (QSR 820.75)**		
14.1	Are methods of processing and testing validated?	Yes, methods of processing and testing are validated. See example of (XXXXXXX) Process validation of injection molding process conducted between xxxx2-02-10 to 27th.	C
14.2	Are there procedures defining validations?	Yes, procedures, SOPs describing in file (XXXXXXX) how process validation will be conducted.	C
14.3	Are training records for people performing validations up-to-date?	Yes, a cross function team of 4 people were involved in the validation of the Injection molding process. They are from Technical, QC, Manufacturing, MR.	C
14.4	Does raw data from validation activities document: - Date - Personnel - Major equipment - Control method	Yes, data such as product name, mold number (Upper body #85, Lower body #86), Injection Machine number (#KHS001, Model #HXF126), plastic raw material lot used # 20121108 etc was defined in the page 3/18 of the file (XXXXXXX). Injection parameters were also defined page 4/18, including cross function team of 4 people to conduct the validation. Product size + tolerances, acceptance level of appearance as per standard FIC-24. The result of IO validation, OQ, PQ are maintained.	C
14.5	If changes have been made to the equipment and process, has a determination been made on revalidations?	The procedure of process validation defineed a method to follow if change happen. But for this case reviewed, no change happened.	C
15	**Receiving, In-Process and Finished Device Acceptance (QSR 820.80, 820.86)**		
15.1	Are receiving logs up-to-date?	Yes, incoming inspections are conducted on each received lot of plastic material, packaging material, label material etc. Records are available, identifiable to each PO# and lot#, date, personnel.	C
15.2	Raw materials reflect acceptance status.	Yes, there is a master list of DHR in the sheet #QR-15-01B, with contents record of IQC, IPQC, PQC, FQC, samples and sterilization.	C
16	**Inspection, Measuring, and Test Equipment (QSR 820.72)**		
16.1	Is the status of all M & TE identified?	Yes, the factory maintains a list of all measuring and test equipment in the sheet (XXXXXXX) , with detail of Equip#, name, model, user name, calibration frequency, Last/Next calibration date. Calibration tag is visible on each equipment, both for measuring of product or measuring process parameter, see photo#29. For Equip for temperature control# xxxv certificate # xxx, or Pressure control xxx / Certificate xxx.	C

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16.2	Are M & TE stored to prevent invalidation of calibration?	M & TE is properly maintained with their calibration tag to prevent for invalid use. See photo# 29.	C
16.3	All measurements and specifications have tolerances where necessary.	Process parameters have tolerances been specified and documented in the parameters sheet.	C
16.4	Is equipment being using within its limitations?	Yes, all equipment are used as defined within their limitations range, see photo #28	C
17	**Device Labeling (QSR 820.120)**		
17.1	Are all labels controlled properly:: - locked up - identified in a procedure - control #'s	Yes, labels are controlled as required in the procedure xx, firstly at the incoming inspection, during labeling process and packaging, and at the final inspection. Records are available in the DHR file.	C
17.2	Is everything that should have labels, labeled?	Yes, the label is correctly identified. For example Ref.#####， Lot #######A, label lot# xxx-07 for product name. See photo #24, $25.	C
17.3	Is FIFO practiced?	Yes, FIFO is practiced, in manual method. Purchasing of material is conducted be order after contract review is approved, and only those materials are on site.	C

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18	**Non-Conforming Product (NCP)**		
18.1	Is rejected product properly labeled, and or quarantined?	Yes, NCP are identified, by isolation in red boxes as indicated in the procedure (XXXXXXX) . Every machine at Injection workshop, at the welding process room, and packaging has Red boxes available to store NCP, see photo #31. Red boxes are located around blues boxes in which GOOD parts should be putted. There is opportunity to mix parts.	I
18.2	Has NCP been properly evaluated?	All NCP will be collected in daily basis, and categorized to each type of defect, such injection, welding process etc; this data will be use for root cause evaluation as required in the procedure (XXXXXXX) .	C
19	**Corrective and Preventive Action (QSR 820.100)**		
19.1	Check log sheets to ensure out of specification (OOS) temperatures have a CAR.	The CAPA is conducted as per procedure (XXXXXXX) , the factory maintains a list of 34 CAPAs, which include NCF issues from internal audit, on site observation such as process parameter deviation, NCP, client's complaint.	C
19.2	Check CAR log to see if the department has any CAR's that are not resolved.	Each CAPA has number, responsible department in charge for investigation or root cause, and corrective action and preventive action written a separate CAPA report	C
19.3	Check corrective actions for effectiveness.	Basically all CAPA are effective and closed, for example of CAPA # 4C6161212CO.	C
20	Device Packaging, Handling, and Storage Distribution (QSR 820.130, 820.140. 820.150, 820.160)		
20.1	Are sterile items stored to prevent contamination?	Yes, sterile items are maintained and stored at the sterilization work place, totally separated to others product that are in workshop A4, as required in the procedure (XXXXXXX)	C
20.2	Is media that is supposed to be stored in the dark, stored properly?	No such requirement for the audited factory, no media product	C
20.3	Are accepted raw materials and test articles kept separate from product that has not been accepted?	Yes, accepted materials are identified and kept separate.	C
20.4	Look for documentation demonstrating customer's original requirements were met.	The file DMR and DHR of product ###### under lot#####A provide enough evidence demonstrating compliance to customer's original requirement.	C
21	**Quality Audit (QSR 820.22)**		
21.1	Is there a procedure as guidance for the execution of internal audit? Is it conducted on a regular basis?	Yes, the audit is conducted at least once per year. The last internal audit was planned and conducted between xxxx -08-16 ~ xxx-08-25, according to the procedure (XXXXXXX) .	C

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21.2	Does the factory has qualified internal auditors? Do they execute the internal audit independently?	Yes, 5 independent Internal auditor (Mr. YYYY # 07 1355, Mr. ZZZZZ # 05 706) attended to this internal audit, all certified to ISO 13485 and MDD 93/42/EEC.	C
21.3	Is the scope of internal audit documented amd cover all element of ISO 13485, QSR 820, including MDD?	The scope covers requirement of ISO 13485, 21 CFR 820 as written in the audit plan sheet (XXXXXXX) .	C
21.4	Are findings of audit identified and corrective action from previous audit completed?	Minor NCF were found specifically in the issue affecting requirement and safety, and which required to update document (XXXXXXX) , (XXXXXXX) about rules to enforce in the laboratory, training were provided to 4 members working in the laboratory as evidence of correction.	C
	Statistical Techniques (QSR 820.200)		
22.1	Are there any requirements for statistical techniques?	Requirement for statistical techniques are defined in the procedure (XXXXXXX) , and mainly applied to define proper sample plan and acceptance AQL during Incoming Inspection (IQC), In-process Inspection (IPQC) and Final Inspection (FQC).	C
22.2	Statistical techniques can be found in: □ - Customer specifications □ - SOP's □ - Reference Standards □ - Acceptance Criteria (i.e. sampling plans)	Every Inspection work instruction has defined statistic method to use, and the number of sample randomly (ie, GB2828) selected is mentioned in the record. Statistic method is also use to categorize failure and calculate defect rate in monthly basis.	C

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Photo 1: Main Gate	Photo 2: External View of Workshop
Photo 3: Record of Opening / Closing Meeting	Photo 4: Integrity Declaration
	

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Photo 5: Documentation (Procedure, QM)		Photo 6: List of 41 procedures
INSERT PHOTO HERE		INSERT PHOTO HERE
Photo 7: Record of cument change / distribution		**Photo 8: Organization Chart**
INSERT PHOTO HERE		INSERT PHOTO HERE

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Photo 9: Responsibilities / Authorities		Photo 10: Nomination Letter of MR.

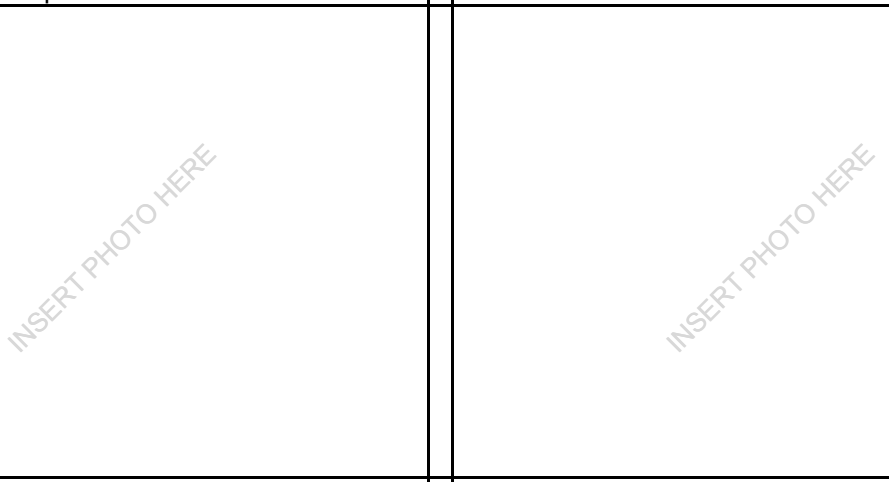



Photo 11: Employee Training Plan		Photo 12: Record of Training

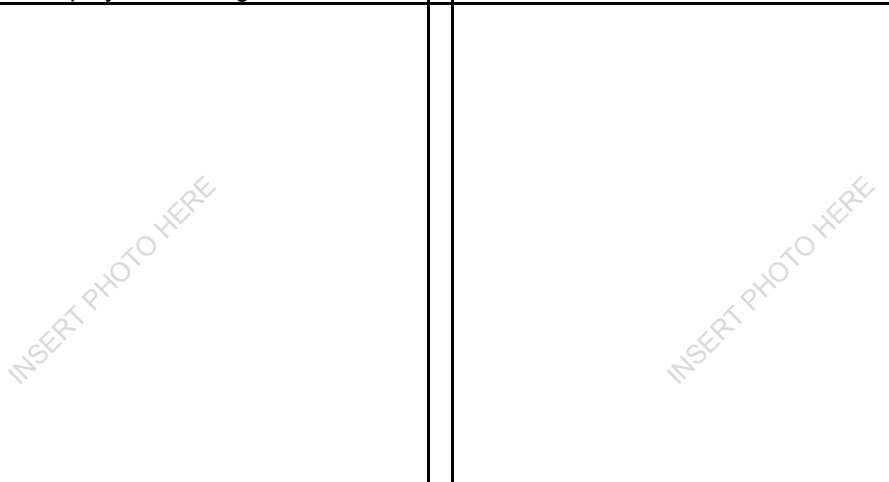



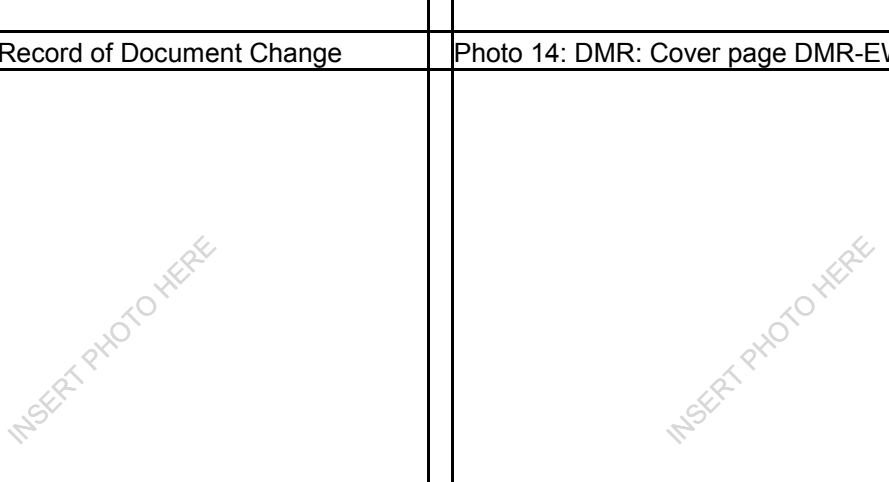
Photo 13: Record of Document Change		Photo 14: DMR: Cover page DMR-EW-01 of #CEB02
		

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Photo 14: DMR: Menu of Product #CEB02		Photo 14: DMR: Manufacturing Flow Chart of CEB02
Photo 14: DMR: Drawing of product #CEB02		Photo 14: MR: List of related international standard
Photo 15: DHR: Cover page of the lot#081515A		hoto 16: DHR: List of record of DHR file of lot#081515

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Photo 17: DHR: Sample of labeling of lot#081515A		Photo 18: DHR: List of raw materials with their lot# used for the production of Lot#081515A
Photo 19: DHR: Record of in-process inspection at Injection machine #KNS-001, KNS-009, KNS-209		Photo 20: DHR: Record of environment control

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INSERT PHOTO HERE	INSERT PHOTO HERE

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Photo 21: Injection Workshop		Photo 22: Welding Process
INSERT PHOTO HERE		INSERT PHOTO HERE
Photo 23: Component and welded part (Only for illustration)		Photo 24: Semi-Finish Labeled
INSERT PHOTO HERE		INSERT PHOTO HERE
Photo 24: Semi-finish labeled with lot# 20151024		Photo 24: Carton Labeled
INSERT PHOTO HERE		INSERT PHOTO HERE

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Photo 25: Labeling in the plastic raw material		Photo 25: Labeling in the plastic raw material
INSERT PHOTO HERE		INSERT PHOTO HERE
Photo 25: Labeling in the plastic raw material with lot#		Photo 26: Work Instruction visible on site at the Injection Machine
INSERT PHOTO HERE		INSERT PHOTO HERE
Photo 26: Work instruction visible on site at the Injection Machine		Photo 26: Work instruction visible on site at welding machine

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Photo 27 How to be weared before enter in the clean room (Injection + Welding + Packaging)		Photo 27: Photo showing how operators are weared at the packaging process.
Photo 28: Calibration Plan and Status		Photo 29: Calibration Tag on Welding Machine
Photo 30: Maintenance Plan		Photo 31: NCF stored in red boxes

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Photo 31: NCF stored in red boxes		Photo 32:
Photo 32: Performance of FQC		Photo 32: Customer Complaint
Photo 32: Supplier Performance		