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|  ECHOSSENS | DISTRIBUTOR AFTER-SALES SERVICE AUDIT | QF 111.6 |
| | | Audit Number: |


| AUDIT IDENTIFICATION | |
|--|---|
| DISTRIBUTOR | CENCOMEX |
| Distributor adress | Santiago |
| Covered territory: | Chili |
| Persons met: | Cristian Yanez |
| Audited departments: | Service, distribution records and customer complaints |
| Auditor: | Olivier Boschat |
| Audit date: | 19/03/2018 |
| ISO company? <i>(ISO 9001, ISO 13485, ...)</i> | <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES (please ask ISO certificate copy) |

LEGEND:


✓ C: Compliant

✓ NC: Non-compliant

✓ Note: To be monitored next audit

 **Check records** for at least one serial number: customer contact → internal handling → feedback to customer → information to Echosens, if **customer complaints** and **service report**

Pictures/documents can be added, if needed.

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| | | Audit Number: |

Point I:

Organisation

✓ C: Compliant

✓ NC: Non-compliant

✓ Note: To be monitored next audit

| Criterion 1: Functional organisational chart | C | NC | Note |
|--|---|----|------|
| <i>Brief description of actions taken, positive points, sensitive points:</i> Chart witnessed | C | | |
| Criterion 2: Identification of functional positions (all positions in contact with customer: installation, training, traceability, complaints, service...) | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> Jaikel Costero – service field engineer beginning Andres Yanez – service field engineer 6 years - | C | | |

Point II:


Human resources

✓ C: Compliant

✓ NC: Non-compliant

✓ Note: To be monitored next audit

| Criterion 1: Skills required for the position (education, background and experience) | C | NC | Note |
|--|---|----|-----------------|
| <i>Brief description of actions taken, positive points, sensitive points:</i> Jaikel Costero – Ing Biomedico Andres Yanez – Tec Sistemas Informatico Sebastian Rojas - Tec Sistemas Informatico Nelson Reyes - Tec Electronico Bruno leyton - Tecnico Electronico | C | | |
| Criterion 2: Check of training program and records for the activities of the position | C | NC | Note |
| <i>Check records</i> <i>Brief description of actions taken, positive points, sensitive points:</i> Jaikel will be trained before summer by Higinio | | | To be monitored |

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|---|---------------------------------------|---------------|
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| | | Audit Number: |

Point III:


Infrastructure and work environment

✓ C: Compliant

✓ NC: Non-compliant

✓ Note: To be monitored next audit

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|--|-------------------------------------|-------------------------------------|-----------------|--|--------|-------------------------------------|---------|-------------------------------------|--------|-------------------------------------|---------|-------------------------------------|------------|--|------------|-------------------------------------|---------------|-------------------------------------|---|--|----------------------------------|
| Criterion 1: Check that the environment satisfies the requirements for after-sales service calls | C | NC | Note | | | | | | | | | | | | | | | | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> Service performed in hospitals Cristian to purchase an ESD carper | | | To be monitored | | | | | | | | | | | | | | | | | | |
| Criterion 2: Check that the environment satisfies the requirements for FS storage | C | NC | Note | | | | | | | | | | | | | | | | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> <table><tr><td>Prevent damage</td><td><input checked="" type="checkbox"/></td></tr><tr><td>Keeps away from</td><td></td></tr><tr><td>- Fire</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Water</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Pest</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Other</td><td><input checked="" type="checkbox"/></td></tr><tr><td>Control of</td><td></td></tr><tr><td>- Humidity</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Temperature</td><td><input checked="" type="checkbox"/></td></tr></table> | Prevent damage | <input checked="" type="checkbox"/> | Keeps away from | | - Fire | <input checked="" type="checkbox"/> | - Water | <input checked="" type="checkbox"/> | - Pest | <input checked="" type="checkbox"/> | - Other | <input checked="" type="checkbox"/> | Control of | | - Humidity | <input checked="" type="checkbox"/> | - Temperature | <input checked="" type="checkbox"/> | C | | |
| Prevent damage | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Keeps away from | | | | | | | | | | | | | | | | | | | | | |
| - Fire | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Water | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Pest | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Other | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Control of | | | | | | | | | | | | | | | | | | | | | |
| - Humidity | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Temperature | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Criterion 3: Check that the environment satisfies the requirements of the calibration bench (specify bench serial number) | C | NC | Note | | | | | | | | | | | | | | | | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> <table><tr><td>Prevent damage</td><td><input checked="" type="checkbox"/></td></tr><tr><td>Keeps away from</td><td></td></tr><tr><td>- Fire</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Water</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Pest</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Other</td><td><input checked="" type="checkbox"/></td></tr><tr><td>Control of</td><td></td></tr><tr><td>- Humidity</td><td><input checked="" type="checkbox"/></td></tr><tr><td>- Temperature</td><td><input checked="" type="checkbox"/></td></tr></table> | Prevent damage | <input checked="" type="checkbox"/> | Keeps away from | | - Fire | <input checked="" type="checkbox"/> | - Water | <input checked="" type="checkbox"/> | - Pest | <input checked="" type="checkbox"/> | - Other | <input checked="" type="checkbox"/> | Control of | | - Humidity | <input checked="" type="checkbox"/> | - Temperature | <input checked="" type="checkbox"/> | C | | |
| Prevent damage | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Keeps away from | | | | | | | | | | | | | | | | | | | | | |
| - Fire | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Water | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Pest | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Other | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Control of | | | | | | | | | | | | | | | | | | | | | |
| - Humidity | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Temperature | <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Criterion 4: Check that the environment satisfies the requirements for the storage of replacement parts | C | NC | Note | | | | | | | | | | | | | | | | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> <table><tr><td>Prevent damage</td><td><input type="checkbox"/></td></tr><tr><td>Keeps away from</td><td></td></tr><tr><td>- Fire</td><td><input type="checkbox"/></td></tr><tr><td>- Water</td><td><input type="checkbox"/></td></tr><tr><td>- Pest</td><td><input type="checkbox"/></td></tr><tr><td>- Other</td><td><input type="checkbox"/></td></tr><tr><td>Control of</td><td></td></tr><tr><td>- Humidity</td><td><input type="checkbox"/></td></tr><tr><td>- Temperature</td><td><input type="checkbox"/></td></tr></table> | Prevent damage | <input type="checkbox"/> | Keeps away from | | - Fire | <input type="checkbox"/> | - Water | <input type="checkbox"/> | - Pest | <input type="checkbox"/> | - Other | <input type="checkbox"/> | Control of | | - Humidity | <input type="checkbox"/> | - Temperature | <input type="checkbox"/> | | | To be monitored (no spare parts) |
| Prevent damage | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Keeps away from | | | | | | | | | | | | | | | | | | | | | |
| - Fire | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Water | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Pest | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Other | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| Control of | | | | | | | | | | | | | | | | | | | | | |
| - Humidity | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |
| - Temperature | <input type="checkbox"/> | | | | | | | | | | | | | | | | | | | | |




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|--|---------------------------------------|---------------|
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Point IV:
Control of service

✓ C: Compliant

✓ NC: Non-compliant

✓ Note: To be monitored next audit


| | | | | |
|--|------------------------|--|----|---------------------|
| Criterion 1: Check workflow of aftersales service | | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | | |
| Under warranty | Under contract service | No warranty and contract | | |
| No database but each customer has service history (scanned intervention form) on a folder sorted out by name | N/A | A quote is issued by the sales department and is stored in the customer folder | C | |
| EPICUR will be implemented to monitor all this | | | | |
| Criterion 2: Check availability of work instructions | | C | NC | Note |
|  Check records | | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | | |
| Echosens technical notes are available and used  | | C | | |
| Criterion 3: Check availability of technical characteristics of machines | | C | NC | Note |
|  Check records | | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | | |
| Cristian to download brochures and add them to the technical folder | | | | Has to be monitored |
| Criterion 4: Check availability of appropriate tools and measuring instruments | | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | | |
| Multimeter OK (not sent to national laboratory) Need torque screwdri Electrical tester FLUKE 368 to perform electrical tester, has to be evaluated | | | | As to monitored |
| Criterion 5: Check availability of stock of replacement parts | | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | | |
| No spare parts | | | | As to monitored |

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Point V:
Identification and traceability

✓ C: Compliant ✓ NC: Non-compliant ✓ Note: To be monitored next audit

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|---|---|----|--------------------|
| Criterion 1: Check the traceability of devices and identification of sites (distribution records) <i>📁: Check records</i> | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> Carolina silva tells that all installation certificates are sent to the web (to be checked with Anthony) Installation certificates are available <input type="checkbox"/> | | | As to be monitored |
| Criterion 2: Check the traceability of service actions <i>📁: Check records</i> | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | C | | |
| Criterion 3: Check the traceability of calibrations <i>📁: Check records</i> | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | C | | |
| Criterion 4: Check compliance with acceptance criteria during servicing of machines <i>📁: Check records</i> | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> Echosens preventive maintenance check-list is used <input checked="" type="checkbox"/> | C | | |
| Criterion 5: Check record of electrical test on serviced devices <i>📁: Check records</i> | C | NC | Note |
| <i>Brief description of actions taken, positive points, sensitive points:</i> Electrical safety tester is available <input type="checkbox"/> check if clamp is suitable for electrical tests and if yes can be extended to FS | | | As to be monitored |

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Point VI:

Supervision and measurement

✓ C: Compliant

✓ NC: Non-compliant

✓ Note: To be monitored next audit

| | | | |
|--|---|--------|------|
| Criterion 1: Check the metrological tracking of measuring instruments | C | NC | Note |
|  Check records | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | |
| Nothing sent to national laboratory | | N C | |
| Criterion 2: Faulty devices and parts: identification and workflow | C | NC | Note |
|  Check records | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | |
| No spare parts | | N C | |



Point VII:

Customer complaints and Vigilance

✓ C: Compliant

✓ NC: Non-compliant

✓ Note: To be monitored next audit

| | | | |
|--|---|----|-------------------------------------|
| Criterion 1: Check workflow of customer complaints | C | NC | Note |
|  Check records | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | As to be mo nito red |
| Cristian volunteer to be in charge of vigilance at CENCOMEX, will be contacted by Katiane | | | |
| Each customer complaint is informed to Echosens <input type="checkbox"/> | | | |
| Criterion 2: Check records of customer complaint investigation | C | NC | Note |
|  Check records | | | |
| <i>Brief description of actions taken, positive points, sensitive points:</i> | | | As to be mo nito red |
| Complaint date <input type="checkbox"/> | | | |
| Model and serial number <input type="checkbox"/> | | | |
| Customer <input type="checkbox"/> | | | |
| Complaint description <input type="checkbox"/> | | | |
| Patient /user impact <input type="checkbox"/> | | | |
| Complete date <input type="checkbox"/> | | | |
| Results of investigation <input type="checkbox"/> | | | |
| Corrective action <input type="checkbox"/> | | | |
| Reply to customer <input type="checkbox"/> | | | |
| See above | | | |
| Each customer complaint investigation is informed to Echosens <input type="checkbox"/> | | | |



DISTRIBUTOR AFTER-SALES SERVICE AUDIT

QF 111.6

Audit Number:

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| Criterion 3: Check workflow if patient / user impact (vigilance) | C | NC | Note |
| Check records <i>Brief description of actions taken, positive points, sensitive points:</i> Person in charge of vigilance: See above Each vigilance case is informed to Echosens <input type="checkbox"/> | | | |

| Corrective and preventive actions | | |
|-----------------------------------|-----------------|-----------------------|
| Description | Deadline (date) | Corrective Action No. |
| | | |
| | | |
| | | |
| | | |
| | | |

| | Auditor | Audited person | Quality department |
|-----------|------------|----------------|--------------------|
| Name | BOSCHART | Cristian Yenez | |
| Signature | | | |
| Date | 15/03/2019 | 13/03/2018 | |