AUDIT PLAN

Organization No.	Scheme	Audit Type	Audit No.
PCS 01095.01	**Product Certification**	**Surveillance**	**03**

Name: **PT. CHITOSE INTERNASIONAL TBK.**

Address: Jl. Industri III No. 5 RT.001 RW.008, Utama, Cimahi Selatan, Cimahi, Jawa Barat - Indonesia

Audit Date(s): April 29th-30th,2024

Audit Objectives: To ensure that the quality system and product within scope meet the requirement of Sucofindo, CPKAB (PermenKes No. 20 Tahun 2017), PermenKes No. 1189/MENKES/PER/VIII/2010 and the product standard SNI IEC 60601-1:2014, SNI IEC 60601-2-52:2014 & Skema BSN No. 5 Tahun 2021 (Sektor Peralatan dan Produk Penanganan Kesehatan).

Scope (Category): **A. Tempat Tidur Pasien Non Elektrik** *(Non-Electric Medical Beds)*

No.	**MODEL** *(Type)*	**SPESIFIKASI** *(Specification)*
1	CB-001	Manual Tanpa Crank
2	CB-001-D	Manual Tanpa Crank
3	CB-002	Manual Tanpa Crank
4	CB-002-D	Manual Tanpa Crank
5	CB-135-D-ST	Manual 1 Crank, 1 Cylinder
6	CB-3003-D-ST	Manual 3 Crank
7	CB-3011-D-ST	Manual 1 Crank, 1 Cylinder
8	CB-3012-D-ST	Manual 2 Crank, 1 Cylinder
9	CB-3012-D4-ST	Manual 2 Crank, 1 Cylinder
10	CB-003 (STRECHER)	Manual 2 Crank
11	CB-7011-D	Manual 1 Crank, 1 Cylinder
12	CB-7012-D	Manual 2 Crank, 1 Cylinder
13	CB-7003-D	Manual 3 Crank
14	OPTIMUS 1M	Manual 1 Crank
15	OPTIMUS 2M	Manual 2 Crank
16	OPTIMUS 3M	Manual 3 Crank
17	RN DS01M	Manual 1 Crank, 1 Cylinder
18	RN DS03M	Manual 3 Crank
19	Saglik MN	Manual 3 Crank

B. Tempat Tidur Pasien Elektromedik *(Electric Medical Beds)*

No.	MODEL *(Type)*	SPESIFIKASI *(Specification)*
1	CB-3300-T	230V, 50/60Hz, IPX4, Kelas II *(Class II)*
2	CB-0733-T	230V, 50/60Hz, IPX4, Kelas II *(Class II)*
3	OPTIMUS 3E	230V, 50/60Hz, IPX4, Kelas II *(Class II)*
4	RN DS03E	230V, 50/60Hz, IPX4, 345VA, Kelas II *(Class II)*
5	Saglik MT	230V, 50/60Hz, IPX4, 345VA, Kelas II *(Class II)*

(Please make sure there will be production process of the above model/s and products are available for sampling and evaluation).

Sector Code: 01.02

Not Applicable Clause(s): None

Audit Team: Muhamad Faizal Karim (MF) / ATL/PPC

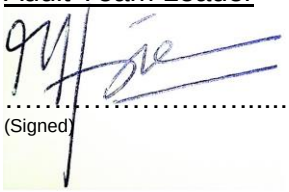
Assessor KAN

Relevant Documentation:
- Organization Policy and Objectives (Quality, Environmental, Safety & Health, Food, Product, Information Security, etc).
- Manual and Procedures as per CPAKB (PermenKes No. 20 Tahun 2017
- Other related documents to ensure the effectiveness of planning, Operation and control of its processes.
- Records as per CPKAB (PermenKes No. 20 Tahun 2017)

Facilities:
- Room for opening & closing meeting & report writing.
- Personnel concerned with audit subject.
- Management representative to provide overall assistance.
- Any other facilities necessary as organization's requirements.

Report Distribution:
1. Organization to be audited (original)
2. Audit Team (copy)

Audit Team Leader



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(Signed)

M Faizal Karim
(Name)

23-April-2024
(Date)

Detail of Audit Plan

Date/Time	Functions / areas / Department / activities to be audited (include related requirements)	Auditor(s)
29/04/2024	**1st Day**	
09:00	**Opening Meeting**	All
09:00	**Management Representative, Panel Audit, Document Controller:** Management Review, Measurement, Analysis and Improvement, Measurement & Monitoring of Customer Satisfaction, Analysis of Data & Continual Improvement, Internal Audit, Corrective and Preventive Action, Control of Document & Control of Record, Customer complaints Actions to address risks and opportunities Documented information	MF
12:00	**Break**	
13:00	**Product Realization for Electric Medical Beds & Non-Electric Medical Beds:** Quality plan, Control and monitoring of production, Production records of the applied models, Control of non-conforming product, Control of incoming material, In-process inspection, Outgoing inspection, **Calibration** Control of monitoring and measuring devices	MF
15:30	**End of audit day 1**	

Date/Time	Functions / areas / Department / activities to be audited (include related requirements)	Auditor(s)
30/04/2024	**2nd Day**	
09:00	**Product Realization for Electric Medical Beds & Non-Electric Medical Beds** *(cont'd)***:** Quality plan, Control and monitoring of production, Production records of the applied models, Control of non-conforming product, Control of incoming material, In-process inspection, Outgoing inspection, **Calibration** Control of monitoring and measuring devices	MF
10:30	**Purchasing Process** Purchasing Process & Information, Selection & Evaluation of supplier	MF
12:00	**End of Audit**	
13:00	**Sampling see annexure 1** **Evaluation and testing of product:** Review of product design and drawing with type test report	MF

13:30	**Reporting**	MF
14:30	**Closing Meeting**	MF
15:30	**End of Audit**	ALL

ANNEXURE-1
SAMPLING PLAN

No.	Model	QTY	Location
1	CB-002	1 unit	Factory Warehouse
2	CB-003 (STRECHER)	1 unit	**Production**
3	CB-7012-D	1 unit	Factory Warehouse
4	Saglik MT	1 unit	**Production**

Note:

1. Sampling plan maybe changed depend on verification during audit
2. Applicant/Importer/Manufacturer shall be responsible for the submitted product specification, in case of any inconsistency, additional tests / sample / charges may apply