Medical Management Systems & Notified Body

Audit Report

UL LLC

on behalf of

Polish Centre for Testing and Certification

Arkray Healthcare Pvt Ltd
Plots No. 336, 338 and 340
Road No. 3, G.I.D.C., Sachin, Dist. Surat
Gujarat 394 230 INDIA
File: A14752
Order: 13752202

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Audit Information

Audit Dates	From	2021-04-05	To	2021-04-09	Total Onsite Days 9.5
Audit Type	Triennial Recertification Audit - Remote				
Audit Team	Sushil Bhardwaj		Lead Auditor		
	P. Suviharan Willington		Auditor		

Management Representative Mr. Devanshu Desai, Manager QA and Assistant MR
Representative's Email/Phone Devanshu.desai@arkray.co.in / +91-9998826841

Audit Objectives
Evaluation of the effectiveness of the management system in meeting its specified objectives.
Identification of areas for potential improvement in the management system.
Determination of the continued conformity of the management system in the following programs:
ISO 13485:2016/EN ISO 13485:2016

To evaluate the continued capability of the management system to ensure compliance with the following medical regulatory requirements:
European Directive concerning In-Vitro Diagnostic Devices 98/79/EC Annex IV

Audit Criteria
The following documents were used as criteria from which the objective evidence collected during the audit was assessed:
EN ISO 13485:2016, IVDD (98/79/EC), UL Program Requirements including use of the UL Registered Firm Mark and Accreditation Body Marks 00-MB-C0032, Manufacturers Quality Management System Policies, Procedures and Quality Objectives.
Reference Documents
In addition to the above criteria the following documents were used as references (in addition to those listed herein equivalent national versions of ISO and IEC standards may also be used):
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Audit Language
The audit was conducted in English.

Sites Covered by this Audit

1-1	Arkray Healthcare Pvt. Ltd Plots No. 336, 338 and 340, Road No. 3, G.I.D.C Sachin, Dist., GJ 394 230 INDIA
2-1	Arkray Healthcare Pvt Ltd, C-90, Bldg. No-5, Akshay Mittal Ind. Premises Co-Op Soc. Ltd., , Near Marol Naka, , Andheri Kurla Road, Andheri East Mumbai, Maharashtra 400059 INDIA

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Scope of Registration

1434-IVDD-377/2019 - IVDD A4 exc 4 and 6
Per Current Certificate:
Blood Glucose Test Strips for self-testing

1029.190709 - ISO 13485:2016
Per Current Certificate:
The design, development and manufacture of in-vitro diagnostic reagents, test kits used in the diagnosis and detection of autoimmune status, blood analytes, blood grouping, cardiac markers, coagulation, compatibility testing, disease status, immune status, transmissible agents, microbiology, serology tests and self-testing.

The manufacture, installation and servicing of in vitro diagnostic biochemistry analyzers.

Purchase for resale, installation and servicing of clinical diagnostic analyzers.

Purchase for resale of diagnostic reagents and test kits.

Clause Exclusions	None
Clause Non-Applications	7.5.5, 7.5.7, 7.5.9.2
Company Description	Arkray Healthcare Pvt. Ltd. designs and manufactures their In-vitro diagnostic reagents, test kits under their business name, Arkray Healthcare Pvt. Ltd. Arkray Healthcare Pvt. Ltd. conducts single shift. The Senior Management is Mr. Ryosuke Kameyama who is President & CEO, Mr. Shaligram Dodia who is Factory Director. Mr. Devanshu Desai who is Manager - QA and Asst. Management Representative. Company Identity: Company operates as Arkray Healthcare Pvt. Ltd., a single entity company

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Process Summaries

Process **Management Subsystem**
Clauses Assessed **4.2.1, 4.2.2, 5.3, 5.4.2; 5.1, 5.5**
Area Visited Quality - General
Person(s) Interviewed
Devanshu Desai—Manager QA & assistant MR
Bhavin Mistry – Assistant manager QA

Process Documents Assessed:
Quality Manual: QSM/AHPL-01, Rev. 10, date 01-03-2021
Quality Policy Annexure 3, Rev. 10, date 01-03-2021

Discussion of Findings
There is a documented quality manual. The Quality Manual's scope is defined and defines the appropriate regulatory requirements. The exclusions and non-applications are defined and justified. The quality manual does have a reference to the documented procedures, a description of the interaction of processes, and structure of the documentation.

Quality planning is conducted for changes to the QMS. There is a defined process for notifying UL of significant changes to the QMS per 00-MB-C0032. The quality policy is defined and is applicable for the company. Top management has documented the interrelation of all personnel. Feedback on the QMS is communicated to the staff. The management representative is defined and reports the effectiveness of the QMS to top management.

The quality management system does apply methods of a risk based approach. When changes occur to the quality management system processes, they are evaluated for their impact on the quality management system and medical devices produced.

The Authorized Representative is defined and the contract does define their responsibilities.

Records sampled:
Quality Manual Defined Regulatory Requirements: ISO 13485 , IVDD (98/79/EEC)

Quality Plan records:
Combaids HIV 1+2 Immunodot Test (NACO)
Crystal HBsAg Device Rapid Test
Crystal Vc
Gluocard Vital Test Strips
Microscreen HBsAg Elisa
Signal HCV Flow ThroughTest

Significant QMS change reporting: no significant change

Organization Chart: OP/MD/G10.2, Ver. 34, date 01-04-2021

Risk Management Policy: RS/F/027, Rev. 05, date 01-12-2020

Risk Based Approach methods:

Sr. No.	Stages at which risk analysis / risk management performed
1.	Design stage
2.	Product validation stage
3.	New equipment purchase / installation

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4.	Change control – Document, product, method, specification, Batch production and control record
5.	Nonconformity assessment
6.	Corrective action process
7.	Software validation process
8.	Identification of equipment criticality at the time of introduction

Impact Assessment records:

Sr. No.	Stages at which risk analysis / risk management performed
1.	Product validation stage
2.	New equipment purchase / installation
3.	Change control – Document, product, method, specification, Batch production and control record
4.	Nonconformity assessment
5.	Corrective action process
6.	Identification of equipment criticality at the time of introduction

Records of staff communication:
Email dated January 22, 2021, Subject Training program—knowledge of prohibition act 1949and poison act, from: Khushboo Patel (HR) to all department heads.

Email dated February 12, 2021, Subject NC board meeting, from Bhavin Mistry- Assistant manager QA to all concerned

Authorized Representative: Arazy Group GmbH, Germany
Authorized Representative Contract Date: 2020-02-20

Sampling was conducted on 6 of approximately 12 quality plans generated since the previous audit.

The quality manual is organized and covers all of the regulatory requirements within the scope. The management process involving the quality manual, outsourced processes, quality policy, quality planning and management responsibilities are in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process **Management Review Process**
Clauses Assessed **5.6, 5.4.1, 6.1, 8.2.5, 8.4, 8.1**
Area Visited Quality - Management Review
Person(s) Interviewed
Devanshu Desai—Manager QA & assistant MR
Bhavin Mistry – Assistant manager QA

Process Documents Assessed:
Management Review Procedure DP/04, Ver. 10, date 23-01-2020
Quality Policy Annexure 3, Rev. 10, date 01-03-2021
Analysis of Data Procedure DP/24, Ver. 06, date 02-07-2018

Discussion of Findings
There is a documented procedure for management review. The new and revised regulatory requirements included the standards and regulations under the scope of the QMS. The quality policy

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and objectives were reviewed during the management review. The quality objectives are measurable and consistent with the quality policy.

There is a documented procedure for analysis of data. Analysis of data is conducted for complaints, feedback, service records, returned product, internal and external audit findings, and data from the monitoring of products, processes, nonconforming products, and suppliers. Statistical techniques are defined in a documented procedure and include the extent of their use.

Records sampled:
Management Review records:
10 MRM agenda, date 18-12-2020,meeting planned on 22-12-2020
Minutes of meeting for 10th MRM date of report 24-12-2020

Management Review frequency: twice in a year
Quality Objectives:
Complaints Results Reagent (Period: Nov. '19 to Oct. '20), target less than 471 in numbers
FY -2020 Cost down status Target V/s Actual
Product delivery Performance FY 2019-20, target 99%

Management Review Input Data:
Complaints Results Reagent (Period: Nov. '19 to Oct. '20), target less than 471 in numbers, received 447 no.'s
FY -2020 Cost down status Target V/s Actual---achieved 237%
Product delivery Performance FY 2019-20, target 99%-- achieved 98.51%
Total feedbacks received for 2020---111 No.'s
Customer complaints for 2020---240 no.'s
Faults Instruments: May '20 to Oct. '20
Dispatch Delivery Performance against TAT
% 2-8°Kits delivered within QA TAT for the month Nov. '19 to Oct. '20—95%

Monitoring and measurement of processes:
Monitoring and measurement of product:
Plate count monitoring (Key Production area)
Particle Count Monitoring: Source of Information: Production •Filling Room –1 (Sterile -0703)—20

Management Review Outputs:
Data analysis records:

Sampling was conducted on 1 of 1 management reviews generated since the previous audit.

The management review is conducted as scheduled. The review includes assessing the quality policy and objectives. There is coverage of the various QMS processes, including audits, corrective and preventive actions, complaints and feedback. The management review process is in conformity with the audit criteria.

Non-Conformities Issued:

☒ **None**	☐ **AR#:**	**Clause Reference**

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Process	**Internal Audit Process**
Clauses Assessed	**8.2.4**
Area Visited	Quality - Internal Audits

Person(s) Interviewed
Devanshu Desai—Manager QA & assistant MR
Bhavin Mistry – Assistant manager QA

Process Documents Assessed:
Internal Audit procedure, DP/20, Ver. 12, date 16-05-2020

Discussion of Findings
There is a documented procedure for internal audits. The internal audit program does define the criteria, scope (including applicable regulatory requirements), methods and reporting and the frequency. Previous audit results were taken into consideration. The internal audit records did identify the processes, area audited and conclusions. The findings from internal audits did have root cause analysis, corrective actions and effectiveness checks performed.
Internal audits did include coverage of the IVDD requirements.

The selection of auditors is defined and auditors do not audit their own work. Personnel responsible for conducting internal audits were found to have the expected qualifications/training to the IVDD requirements.

Records sampled:
Internal Audit records:
Internal audit plan for the period April 2020 to March 2021
Internal audit report dated 15-01-2021 (audit performed from 04-01-2021 to 09-01-2021)
IQA NC's:
IQA 20-21 02 01
IQA 20-21 02 02
IQA 20-21 02 03
IQA 20-21 02 04
IQA 20-21 02 05
IQA 20-21 02 06
IQA 20-21 02 07

Internal Auditor training records:
In-house training on internal audit for ISO 13485:2016, 9001:2015, EC directive 98/79/EC, date of training 24-06-2019, no. of participants 26.

Sampling was conducted on 1 of approximately 1 internal audits generated since the previous audit.

The internal audits did cover all of the elements of the QMS within the scope of the certification. The internal audit process is in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

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Process	**Improvement Process**
Clauses Assessed	**8.5.1, 8.2.2, 7.2.3c,d, 8.2.3, 8.3.3, 8.2.1, 5.2**
Area Visited	Quality –Complaint Handling, Reporting to Regulatory Authorities, Actions in Response to Nonconforming Product Detected After Delivery, Feedback, Customer Focus

Person(s) Interviewed
Devanshu Desai—Manager QA & assistant MR
Bhavin Mistry – Assistant manager QA

Process Documents Assessed:
Customer complaints & feedback procedure, DP/19, Ver. 07, date 15-04-2019
Advisory notices (including product recall) procedure, DP/26, Ver. 07, date 02-07-2018
Vigilance and mandatory reporting procedure, DP/27, Ver. 10, date 01-07-2020

Discussion of Findings
There is a documented procedure for timely complaint handling, including oral complaints, in accordance with applicable regulatory requirements. If an investigation is not performed, the justification is recorded.

If the investigation of complaints determines activities outside the organization contributed to the complaint, relevant information was exchanged between the organization and the external party involved.

There is a documented procedure for providing notification to the appropriate regulatory authorities that meets the timely reporting criteria of adverse events or issuance of advisory notices according to the applicable regulatory requirements.

The nonconforming procedure does include product that is detected after delivery or use has started, and actions taken appropriate to the effects, or potential risks, of the nonconformity.

There is a documented procedure for the feedback process. This feedback does include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process was used as input into risk management. The post-market surveillance for medical devices is consistent with requirements to inform regulatory authorities and notified bodies, as applicable.

The manufacturer does have documented processes in place for identifying advisory notices, reportable events and recalls. These processes do meet the timeframes required by each regulatory authority where the product is marketed. There is a defined process for advisory notices/recalls to be reported to regulatory authorities when necessary and comply with the timeframes and recordkeeping requirements established by participating regulatory authorities.

Records sampled:
Complaint records:

Notification	Ref.. Notification No	Dt of Recpt	Product	Compl..Desc.	Comp.Date
000200019283	CSC/01/2021/001	06-05-2020	<B>signal hiv 3d (10tests) test kit	Invalid result	5/6/2020
000200019284	CSC/01/2021/002	11-05-2020	Fouchet`s reagent (125ml)	Damage to cartoon - leakage of reg. - 01,R/S OK	5/11/2020

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000200019292	CSC/01/2021/003	30-05-2020	Drabkin`s solution (1l)	Leakage - 02 can,R/S OK	5/30/2020
000200019301	RGS/01/2021/008 III	10-06-2020	Lg total protein test kit (100ml)biuret	Getting more color and high result	6/12/2020
000200019346	RGS/01/2021/027 II	14-07-2020	Widal s.typhi antigen set h&o (2x2x5ml)	All result positive,R/S OK	7/14/2020
000200019348	CSC/01/2021/017	17-07-2020	Glucocard vital test strip (blister pack	E01 Error when strip insert in meter,R/S OK	7/17/2020
000200019349	CSC/01/2021/018	17-07-2020	Glucocard vital test strip (blister pack	E01 Error	7/18/2020
000200019369	CSC/01/2021/024	8/4/2020	Signal hiv 3d ver 1.0 (50tests) test kit	False positive result-01 sample,HIV-2 +ve by Signal HIV 3D ver1.0 Test,-ve by CMIA (0.08) test at DCL	8/6/2020
000200019406	RGS/01/2021/052	8/28/2020	Glucocard vital test strip (blister pack	E 13 error,R/S OK	8/29/2020
000200019570	RGS/01/2021/121	11/6/2020	Widal s.typhi antigen set h&o (2x2x5ml)	False positive result	11/11/2020
000200019641	RGS/01/2021/166	12/10/2020	Widal s.typhi antigen set h&o (2x2x5ml)	Breakage,R/S OK	12/11/2020
000200019642	RGS/01/2021/167 I	12/10/2020	AUTOSPAN TURBIGOLD RF TEST KIT (50 ml)	Getting lower value	12/15/2020
000200019643	RGS/01/2021/167 II	12/10/2020	Liquidgold lipase test with multichem 5m	All result high,R/S OK	12/15/2020
000200019988	RGS/01/2021/338	3/31/2021	Widal s.typhi ag set h,o,a(h)&b(h)4x5ml	"O" antigen give false +ve result	

Instruments:

Notification	Date of Not.	EquipName	Compl.Desc	Remark
000300025578	1 Sep 20	INGENIIOUS	PMS (LEAKAGE)	Part replaced
000300025468	21 Sep 20	AUTOCELL PLUS	Vaccum motor fial	Part replaced
000300025454	14 Oct 20	AUTOCELL PLUS	Tube cut by rat(mouse)	Fitment done

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000300025535	27 Oct 20	AUTOCELL PLUS	Breakdown	Part replaced
000300025636	9 Nov 20	AUTOCELL PLUS	Keyboard and mouse not work	Part replaced
000300025742	28 Nov 20	INGENIIOUS	Gain less and resulsts problem	Part replaced
000300025910	15 Dec 20	INGENIIOUS	Aspiration not proper	Cleaned fluid path
000300025802	29 Dec 20	AUTOCHEM XACT PRO	Cuvvet replacement	Part replaced
000300025871	13 Jan 21	INGENIIOUS	Memory error 26	Part replaced
000300025823	27 Jan 21	AUTOCHEM2011	Filter wheel error pms	Clean
000300025881	15 Feb 21	AUTOCHEM NEXGEN	RESULTS variation	Part replaced
000300026018	26 Feb 21	INGENIIOUS	Redo blank error	Part replaced
000300025959	27 Feb 21	INGENIIOUS	Incubation temp high (pms)	Part replaced
000300025998	27 Feb 21	AUTOCHEM NEXGEN	Aspiration not proper(pms)	Part replaced

Reportable Events records: None
Recall records: none
Advisory Notice/FSN Records: none
Feedback records:

- Daksh Pathology, Indore, date of feedback 16-07-2020, satisfactory feedback
- New Ashirwad pathology, date of feedback 16-07-2020, overall good feedback
- Baba diagnostics, Feroke, date of feedback 10-08-2020, good feedback
- Green heals hospital, Silchar, date of feedback 22-08-2020, very good
- G.V.Toyan hospital, Saleem, date of feedback 28-08-2020, satisfactory
- Neera nursing home, Lucknow, date of feedback 12-09-2020, very good
- Baba hospital, Lucnow, date of feedback 12-09-2020, satisfactory
- New spandan diagnostic centre, date of feedback 29-09-2020, good
- JJS KMC, Kannur, date of feedback 16-10-2020, very good
- Kurumaya hospital, date of feedback 05-10-2020, very good

Sampling was conducted on 28 of approximately 100s complaints, and 10 of approximately 100s of feedback generated since the previous audit.

The customer complaint process handles complaints in a timely manner and all necessary information is documented. The vigilance process is documented. The process for reviewing feedback is documented and meets the requirements. The improvement process is in conformity with the audit criteria.

Non-Conformities Issued:

☒ None **☐ AR#:** **Clause Reference**

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Process	**Corrective Action and Preventive Action Process**
Clauses Assessed	**8.5.2, 8.5.3**
Area Visited	Quality - Corrective/Preventive Action

Person(s) Interviewed
Devanshu Desai—Manager QA & assistant MR
Bhavin Mistry – Assistant manager QA

Process Documents Assessed:
Corrective action procedure, DP/28, Ver. 10, date 01-07-2019
Preventive action procedure, DP/29, Ver. 06, date 02-07-2018

Discussion of Findings
There is a documented procedure for the corrective/preventive action process. Evidence of preventive and corrective actions was provided for review. The corrective actions were taken without undue delay. Investigations and root causes are documented. Action plans are developed and effectiveness checks are conducted.

Records sampled:
CAPA records:
- AMICA-2020-002, date 29-08-2020
- AMICA-2020-003, date 26-10-2020
- AMICA-2020-004, date 08-12-2020
- AMICA-2020-005, date 09-12-2020
- AMICA-2020-006, date 25-12-2020

CAPA Reportable Events records:
CAPA Recall records:
CAPA from complaints:
- AMICA-2021-001, date 18-02-2021

Sampling was conducted on 7 of approximately 7 Corrective/Preventive Actions generated since the previous audit.

Corrective/Preventive actions are processed according to the requirements. Root cause and effectiveness checks are performed for each Corrective/Preventive action. Records are accessible and documented per internal requirements. The Corrective/Preventive process is in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process	**Corrective Action and Preventive Action Process – Site 2-1 Warehouse**
Clauses Assessed	**8.5.2, 8.5.3**
Area Visited	Quality - Corrective/Preventive Action

Person(s) Interviewed
Mr. Bankim Desai, Branch Manager - Warehouse

Process Documents Assessed:
DP/28, Ver.10, 01-Jul-2019 Standard for Corrective Action Procedure
DP/29, Ver.06, 02-Jul-2018 Standard for Preventive Action
DP/33, Ver.01,01-Jan-2021 Standard for TrackWise CAPA Control Procedure

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Discussion of Findings
There is a documented procedure for the corrective/preventive action process. Evidence of preventive and corrective actions was provided for review. The corrective actions were taken without undue delay. Investigations and root causes are documented. Action plans are developed and effectiveness checks are conducted.

Records sampled:

No CAPAs generated since last three years.

Corrective/Preventive actions are processed according to the requirements. Root cause and effectiveness checks are performed for each Corrective/Preventive action. Records are accessible and documented per internal requirements. The Corrective/Preventive process is in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process	**Design and Development Process – CL**
Clauses Assessed	**7.1, 7.3.1, 7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6, 7.3.7, 7.3.8, 7.3.9, 7.3.10, 4.2.3**
Area Visited	Engineering - Design and Development, Medical Device File Glucocard Vital Test Strip, REF: 93GS100-50 (CE1434 marked) Crystal HIV, Project Code: 236/1617/RS Crystal Dengue NS1, Project No.: 243/1718/RS

Person(s) Interviewed
Mr. Devanshu Desai, Manager – QA
Mr. Ankur Naik, Asst Manager – R & D

Process Documents Assessed:
DP/08, Ver.10, 02-Jul-2018 Standard for Risk Management
DP/10, Ver.11, 01-Jul-2020 Standard for Design and Development
DP/31, Ver.01, 01-Jan-2021 Standard for TrackWise Change Control Procedure
DP/36, Ver.00, 18-Feb-2019 Standard for Change Control Process
DP/37, Ver.01, 25-Mar-2021 Standard for Manufacturing Transfer Procedure for AFC products

Discussion of Findings
The risk management process is established for product realization and does follow ISO 14971:2007 and EN ISO 14971:2012. Evidence of a risk management plan, risk evaluation, risk control and a risk management report was provided. Software was included within the risk management process.

There is a documented procedure for the design and development medical devices and these devices have been appropriately identified and subject to the regulations. The documented procedure for design and developing medical devices do include design and development stages, review, verification, validation, design transfer, and design changes. When the medical device contains software, the software was part of the design and development process.

Design planning does define the development stages, the design reviews, the verification, validation, and design transfer activities, the responsibilities and authorities, the methods to ensure traceability of design and development outputs to design inputs, and the resources needed including necessary competence.

The design inputs do include functional, performance, usability and safety requirements, according to the intended use of the equipment/device, applicable regulatory requirements and standards,

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applicable output(s) of risk management, and as appropriate, information derived from previous similar designs. The inputs were reviewed for adequacy and approved. The lifetime of the device is defined. We reviewed the classification information and determined that the device is classified correctly. The design inputs are complete, unambiguous, and not in conflict with each other.

The design outputs did meet the input requirements, provide appropriate information for purchasing, production and service provision, contain or reference product acceptance criteria, and specify the characteristics of the product that are essential for its safe and proper use.

The design reviews did occur as scheduled and the records demonstrated the results of design to meet requirements and identify and propose necessary actions. The design reviews did include the identification of the design under review, the participants involved and the date of the review, including impartial participants.

Design verifications were performed in accordance with planned and documented arrangements, including interface with other medical devices. The verifications did include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size.

Design validations were performed in accordance with planned and documented arrangements, including interface with other medical devices. The validations include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. Design validations were conducted on representative product. The rationale for the choice of representative product did include initial production units, batches or their equivalents. Validations were completed prior to release for use of the product to the customer. The design validation data did show that the design meets the specified application and/or intended use.

Clinical evaluations or performance evaluations of the medical device were performed in accordance with applicable regulatory requirements. The process is in a documented procedure.

There is a documented procedure for the transfer of design and development outputs to manufacturing. The outputs were verified as suitable for manufacturing before becoming final production specifications.

There is a documented procedure for design changes. The design changes did determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design changes are reviewed, verified and validated, as appropriate, before being approved. They do include evaluation of the effect of the changes on constituent parts and product in process, inputs or outputs of risk management and product realization processes. They do include a determination of notification to regulatory bodies included in the scope of the QMS. The design change process did include the effect on products previously made and delivered.

There was evidence of a design file for each medical device type or medical device family. The files did include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

The content of the files did include: general description of the medical device, intended use/purpose, and labelling, including any instructions for use; specifications for product; specifications or procedures for manufacturing, packaging, storage, handling and distribution; procedures for measuring and monitoring; requirements for installation; procedures for servicing.

Records sampled:
Risk Management report records:
Severity – Negligible (1), Moderate (3), High (5) and Very High (7)

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Occurrence – Remote – 1 out of >2000 to 20000 (1), Low – 1 out of >1000 to 2000 (3), Moderate – 1 out of >100 to 1000 (5) and High – 1 out of 100 or less (7)
Risk Index Chart
A -Below 21 – Acceptable
R – 21 through 25 – Tolerable Risk
U – Above 25 – Intolerable Risk

RS/F/027, Rev.04 dated 15-Jul-2016 Risk Management
Risk Management Policy
Risk Management Plan for Glucocard Vital Test Strip 93GS100-50 dated 05-May-2017
Intended Use – Device Characteristics dated 05-May-2017
Hazard List -Hazard Identification worksheet for Glucocard Vital Test Strip dated 05-May-2017
Risk Assessment – 43 Hazards identified and out of that 2 of the initial risk index numbers are not acceptable
HZ-1 (Hazard Id.), Biological (Nature of Risk) – Waste (Potential Failure Mode) – Infection to User (Potential Effects of Failure), 7 (Severity), Improper waste handling and disposal of biological waste generated upon completion of test (Potential Causes of failures), 5 (Occurrence), 35 (Risk Index), N-ACC (Acceptability), Proper Instructions given in IFU (Risk Control Method), Included in IFU about disposal of used test strips and lancets as biohazards waste, Laboratory to follow regulatory requirement (Action taken & verification reference, 7 (Severity), Occurrence (1), 7 (Risk Index), ACC (Residual Risk)
HZ-2 (Hazard Id.), User Error (Nature of Risk) – Wrong Diagnosis (Potential Failure Mode) – Deterioration of Patient's Health (Potential Effects of Failure), 7 (Severity), Wring interpretation and reporting of observation (Potential Causes of failures), 5 (Occurrence), 35 (Risk Index), N-ACC (Acceptability), Proper Instructions given in IFU Risk Control Method), Principle, Intended Use, Interpretation/limitations of results, storage condition, warning and precautions (Action taken & verification reference, 7 (Severity), Occurrence (1), 7 (Risk Index), ACC (Residual Risk)
Risk Reduction and Option Analysis Worksheet – HZ-1 & HZ-2
Risk/Benefit Analysis – No residual risks
Risk Reduction Generated Hazard Worksheet – None
Completeness of Assessment Worksheet
Overall Residual Risk Evaluation Sheet
Risk Management Report Signed off on 24-Jun-2017

RS/F/027 Risk Management for Crystal HIV Project Code: 236/1617/RS dated 10-Jan-2020
Risk Management Policy
Risk Management Plan for Crystal HIV Project Code: 236/1617/RS dated 10-Jan-2020
Intended Use – Device Characteristics dated 05-May-2017
Hazard List -Hazard Identification worksheet for Crystal HIV Project Code: 236/1617/RS dated 10-Jan-2020
Risk Assessment – Total 87 Hazards were identified during Risk Assessment, out of which 19 Hazards were found not acceptable. After Risk mitigation 16 Hazards were brought to acceptable level. Remaining 3 Hazards have residual risks for which justification/reduction measures are taken . As below:

HZ-10 (Hazard Id.), In use errors (Nature of Risk) – Deviation from Instruction and Procedure (Potential Failure Mode) – Inconsistent result or nonperformance of test device (Potential Effects of Failure), 7 (Severity), Use of the device for the detection of pathogen not intended for, manipulation in procedure, Inadequate review of IFU before performance, Une of inaccurate product IFU (Potential Causes of failures), 3 (Occurrence), 21 (Risk Index), ACC (Acceptability), Pictorial diagram on kit box, Use of universal IVD symbols in labels, Complete information on procedure and consequences if deviated from the product IFU (Risk Control Method), Pictorial diagram on kit box, Use of universal IVD symbols on labels, User friendly IFU Ver No. 1114/Ver 1.3 Design Dossier file (Action taken & verification reference, 7 (Severity), Occurrence (1), 7 (Risk Index), ACC (Residual Risk)

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HZ-18(2) (Hazard Id.), Raw Material Related (Nature of Risk) – Non-availability of antigen of HIV (Potential Failure Mode) – Product Discontinuation, Product Delay (Potential Effects of Failure), 7 (Severity), Safety stock not maintained (Potential Causes of failures), 5 (Occurrence), 35 (Risk Index), N-ACC (Acceptability), Company has the policy of maintaining safety stock based on the past trend and future business potential (Risk Control Method), Company Policy (Action taken & verification reference, 7 (Severity), Occurrence (3), 21 (Risk Index), ACC (Residual Risk)

HZ-26 (Hazard Id.), Design and Development Related (Nature of Risk) – Inadequate sample panels (Potential Failure Mode) – Non-performance and inconsistent results (Potential Effects of Failure), 7 (Severity), Inappropriate sample panels, the panel may contain special analyte in samples (Potential Causes of failures), 5 (Occurrence), 35 (Risk Index), N-ACC (Acceptability), Relevant sample panels should be selected during the product development to ensure the intended use of the product (Risk Control Method), Design Dossier Files (Action taken & verification reference, 7 (Severity), Occurrence (1), 7 (Risk Index), ACC (Residual Risk)
Risk Management Report Signed off on 04-Feb-2020

Design projects:
No changes in the CE marked devices, One design in completed during last one year and one design is ongoing.

- Glucocard Vital Test Strip, REF: 93GS100-50 (CE1434 marked) – No change
- Crystal HIV, Project Code: 236/1617/RS – Completed
- Crystal Dengue NS1, Project No.: 243/1718/RS – Ongoing

Design records:

Glucocard Vital Test Strip, REF: 93GS100-50 (CE1434 marked)
The Glucocard Vital Test Strip product was designed by Arkray Factory. This design led to the production of electrochemical glucose sensor array for 50 tests on a single strip, currently produced at ApexBio, Taiwan. Arkray India receives these strips from Arkray Factory, Japan as a raw material for production of its Glucocard sigma and Glucocard Vital products, which are single-test strips sold in individual bottles containing 50-strips per bottle.
Arkray has processes in place to design and develop labels and packaging for this product (part of Production Process). Arkray Factory has provided Arkray India Pvt. Ltd. The design and development records, including specifications, stability studies and all other relevant design and development records, which comprise the Glucocard Vital Technical File, previously reviewed by NB.

Crystal HIV, Project Code: 236/1617/RS, Product Code: 51IC106-50, Status Ongoing: Transfer in Progress
Immunochromatographic One Step Rapid Visual Test for Crystal HIV-1/2
RS/F/001 Planning PERT Chart, Annexure DP10.2 dated 18-Dec-2019
RS/F/001 Design Input file, Annexure DP10.1 to Annexure DP10.14 dated 03-May-2017 to 17-Jan-2020
RS/F/018 QC Specifications for Crystal HIV 51IC106-50/10 dated 21-Jan-2020
RS/F/024 Accelerated temperature stability dated 28-Dec-2019
RS/F/008 Draft labels Section D dated 04-Jan-2020
RS/F/008 Draft IFU Section C dated 13-Feb-2020
RS/F/001 Review at each Design stages dated 08-Jun-2017 to 14-Dec-2019
RS/F/008 Verification report dated 15-Jan-2020
RS/F/001 Validation Report dated 14-Aug-2019 to 14-Dec-2019
Transfer:
RS/F/008 Draft labels dated 24-Dec-2019
RS/F/011 Design Transfer Format (Specifications) dated 11-Jan2020
RS/F/022 Design Transfer Format (Master production and control record dated 28-Jan-2020

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PE/F/013 Manufacturing Transfer Master Plan dated 03-Feb-2020
PE/F/012 Product Assessment for Mass Production Readiness dated 04-Mar-2020

Crystal Dengue NS1, Project No.: 243/1718/RS
243/1718/RS Risk management of Crystal Dengue NS1 dated 01-Mar-2019
Design Planning, Input:
Annexure DP10.3 243/1718/RS Design Input file(Information Derived from previous similar product) dated 05-Mar-2019
Annexure DP10.4 243/1718/RS Design Input file(Target Design specification) dated 05-Mar-2019
Annexure DP10.6 243/1718/RS Design Input file(List of applicable standards for labelling, packing, storage and shipping) dated 08-Mar-2019
Annexure DP10.9 243/1718/RS Design Input file (IPR review) dated 30-Nov-2018
Annexure DP10.11 243/1718/RS Design Input file (Verification plan) dated19-Mar-2019
Annexure DP10.12 243/1718/RS Design Input file (Validation plan) dated 25-Mar-2019

Design change records:

CMF No. CM/2020/008 dated 21-May-2020
Earlier: Concentration of stock signal reagent (Code:- 000200001451) is make to 3.0 L
Change: Concentration of stock signal reagent (Code:- 000200001451) is make to 1.5 L
Justification: By reducing the concentration of stock signal reagent 1.5 L, we can increase the production capacity.

CMF No. CM/2020/014 dated 19-Dec-2020
Earlier: Raw material Alpha Ketoglutaric Acid (Code:- 000100000013) is used in the manufacturing of MBK ALT & AST Test Kit
Change: Proposed to change raw material Alpha Ketoglutarate Disodium Dihydrate (Code:- 000100000014) in the manufacturing of MBK ALT & AST Test Kit
Justification: Raw material Alpha Ketoglutarate Acid (000100000013) is not available in the market. So proposal to change the raw material Anhydrous to Di-hydrate in the product recipe. The new material is Alpha Ketoglutarate Disodium Dihydrate (000100000014)

CMF No. CM/2020/015 dated 19-Dec-2020
Earlier: ASO Latex is ready to fill product. Procured raw material from vendor (Biokit) and do filling at AMI.
Change: ASO Latex from other vendor (Sorachim) and required incoming inspection for dilution factor before use.
Justification: (1) Reduce delivery time from 135 days to 30 days. (2) raw material cost is reduced.

Medical device file records:
Product Name - Product Code -Effective Date -Version No.
Glucocard ∑ Test Strips (Blood Glucose Test Strips) - 93GS102-50 – 01-Aug-2020 - 1.0
Glucocard Vital Test Strip (Blood Glucose Test Strips) - 93GS100-50 – 01-Aug-2020 - 1.0

Technical file inputs:
Harmonized Standards
EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15197:2015, EN ISO 23640:2015, EN 13612:2002/AC:2002

Technical file records:
Product Name - Product Code -Effective Date -Version No.
Glucocard Vital Test Strips (Blood Glucose Test Strips) - 93GS100-50 – 01-Aug-2020 - 1.0
- Section III Essential Requirements (ER) Assessment
- Declaration of Conformity dated 19-Jul-2019

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- Reagent Label Version Control 0720/ver 1.3 with CE 1434
- Box Label 0720/ver 1.3 with CE 1434
- IFU 0720/ver 1.3 with CE 1434
- No translations until now

Reviewed all 3 design changes generated since the previous audit.

The design process is detailed and does effectively document the design of the devices. Risk management is considered early in the design of the product and then addressed throughout the life for the device as needed. The design and development process is in conformity with the audit criteria.

Non-Conformities Issued:

☒ **None** ☐ **AR#:** **Clause Reference**

Process **Production Process – CL (Reagents)**
Clauses Assessed **7.1, 7.5.1, 8.2.6, 7.5.2**
Area Visited Production
Person(s) Interviewed
Mr. Devanshu Desai, Manager – QA
Mr. Bhavin Mistry, Asst Manager - QA
Mr. Vipul Naik, Deputy Manager – Production

Process Documents Assessed:
DP/12, Ver.06, 02-Jul-2018 Standard for Control of Production and Provision of Services
DP/13, Ver.08, 25-Mar-2021 Standard for Cleanliness of Product and Contamination Control (Health, Cleanliness and Clothing of Personnel)
DP/21, Ver.06, 02-Ju;-2018 Standard for Monitoring & Measurement of Process
DP/22, Ver.07, 07-Apr-2018 Standard for Monitoring & Measurement of product (Inspection and Testing)
SW/S/022, Ver.13, 04-Feb-2019 Procedure for Production Planning and Control
SW/S/018. Ver.08, 02-Jan-2020 Procedure for Operation, Daily Checking & Calibration of Digital Weighing Balance and Digital Counting Scale
SW/S/031, Ver.04. 02-Feb-2019 Procedure for Cleaning and Operations of Reverse Laminar Air Flow Unit (RLAF)
PP/S/018, Ver.08, 08-Mar-2021 Procedure for Calibration, Operation and Cleaning of pH Meter
PP/S/025, Ver.02, 22-Jan-2019 Procedure for Non-Sterile Filtration of Solution
PP/S/040, Ver.02, 06-Jul-2018 Procedure for Operation and Cleaning of Continuous Band Sealer
PI/S/009, Ver.13, 13-Nov-2020 Procedure for Operation and Cleaning of Strip Cutting Machine
PI/S/023, Ver.12, 12-Apr-2019 Procedure for Operation and Cleaning of Iso Flow Reagent Dispenser for Spraying of Control and Test Reagents and Colloidal Gold Solution
PI/S/078, Ver.03, 30-Jan-2019 Procedure for cutting of Nitrocellulose membrane from sheet
PI/S/082, Ver.02, 20-Nov-2019 Procedure for Operation and Cleaning of Horizontal Flow Wrap Machine (pillow pack) with TTO Printer
PC/S/013, Ver.07, 08-Mar-2021 Guideline for packing activity
PC/S/014, Ver.06, 28-Jan-2019 Operation and Cleaning of Label printing machine
PC/S/017, Rev.09, 28-Dec-2020 Operation and Cleaning of Shrink Wrapping Machine
PC/S/020, Rev.06, 11-Apr-2019 Procedure for Label Printing, Box Printing and Labeling of Reagent Bottle

Discussion of Findings
Production processes are planned, carried out, monitored and controlled to ensure that product conforms to specification. The production planning outputs are suitable for the organization’s method of operations. Methods for the control of production are defined and documented.

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There are documented requirements (procedures, requirements, work instructions, reference materials and measurements) for the production process. This does include the availability and use of suitable infrastructure and monitoring and measuring equipment, labelling and packaging, product release, delivery and post-delivery activities. There are documented requirements for cleanliness of product and the control of contaminated or potentially contaminated product in order to prevent contamination.

Reagents → Raw Materials from stores → Formulation → Quality Control → Filtration → Filling of vials → Storage → Kit packing

Glucocard Strips → Uncut card sensor rows, containers and caps from stores → Strip cutting → Primary packing - Collect the strips into containers and capping → Secondary Packing

Monitoring and measuring of the product is being conducted as defined. Evidence of conformity with the acceptance criteria is maintained. The identity of the person authorizing release of product shall is recorded and records do identify the test equipment used to perform measurement activities. The product risk is considered in the type and extent of product monitoring activities.

Production and service processes are appropriately controlled, monitored, and operated within specified limits and documented in the product realization records. Risk control measures are identified for production processes are implemented, monitored and evaluated.

There are device history records (DHRs) established and maintained for each batch of medical devices. The records are verified and approved, and the devices are manufactured according to the DMRs.

Records sampled:
Production planning methods:
SW/F//067 Four Months Sales Rolling Plan for Domestic
For Export: Last month balance production plan + Three Months Rolling Plan

Production Planning:
Production Schedule For Apr-2021 – Immunology, Sterile, Biochemistry, Micro, Bgm, Sensitivity Disc, Instruments
Production Plan For 07-Apr-2021:

Product Code	Product Name	Lot No	Activity
Biochemistry:			
200000198	Urea Standard 50 mg/dl 2ml	3000065899	Manufacturing
200000200	Urea Standard 250 mg/dl 2.5ml	30000065901	Manufacturing
Immunology:			
51FT102- 50	Signal Hiv 3d Ver 1.0 (50tests) Test Kit	4000024956	Pouching On Ffs M/C
52IC102 -25	Crystal-Hbsag (Device-25tests) Test Kit	4000024949	Manufacturing
Packing:			
17SA428-05	Widal S.Typhi Ag Set H,O,A(H)&B(H)4x5ml	4000024908	Packing
55IC204-25	Parahit Total Ver. 1.0 (Device-25 Tests)	4000024941	Packing
11AS128-10	Spanclone Anti-B Serum (10ml) Monoclonal	4000024970	Packing
11AS109-05	Anti-A1 Lectin (5ml)	4000024879	Packing

Documented cleanliness requirements:
Gowning requirements: booties, coats, hairnets, beard covers and gloves
Bioburden monitoring: Once in four months on air, product and surface

Production records/DHRs:

Batch No, Product REF, Product Name, Quantity, Date of MFG, Date of Expiry

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Self-Testing
4000024683, 99GS999-50, Glucocard Vital Test Strips, 15195 Nos., 03-Feb-2021, 03-Dec-2022

4000024731, 93GS102-50, Glucocard Sigma Test Strips, 15184 Nos, 15-Feb-2021, 15-Dec- 2022
4000024337, 93GS102-50, Glucocard Sigma Test Strips, 7527 Nos, 24-Nov-2020, 24-Sep-2022
Autoimmune Status
4000024410, 51FT102-50, Signal HIV 3D Ver 1.0 (50tests) Test Kit, 328 Nos, 10-Dec-2020, 10-Dec-2022
4000024477, 51SP201-48n, Combaids RS Advantage-St (48tests), 9993 Nos, 23-Dec-2020, 23-Dec-2022
Blood Analytes
4000024304, 11AS109-05, Anti-A1 Lectin (5ml), 3823 No,19-Nov-2020, 19-Aug-2022
4000024625, 11AS109-05, Anti-A1 Lectin (5ml), 1100 No, 23-Jan-2021, 23-Oct-2022
Blood Grouping
4000024694, 11AS127-10, Anti-A Monoclonal, 1304 Nos, 05-Feb-2021, 05-Feb-2023
4000024076, 11AS129-10, Anti-D (Rho) Monoclonal-IgM, 2425 Nos, 08-Oct-2020, 08-Oct-2022
Cardiac Markers
4000023780, 73LS101-25, Autospan Liquidgold CK-NAC (5x5 Ml), 75 Nos,13-Aug-2020, 13-Feb-2022
4000024609, 73LS102-25, Autospan Liquidgold CK-MB(5x5 Ml), 74 Nos, 21-Jan-2021, 21-Jul-2022
Coagulation
4000024880, 98LS100-05, Thrombospan-LS (5ml), 582 Nos, 15-Mar-2021, 15-Mar-2022
4000024475, 98LS100-05, Thrombospan-LS (5ml), 590 Nos, 22-Dec-2020, 22-Dec-2021
Compatibility Testing
4000024710, 96MB100-10, MBK G-6PD (Qualitative) Test Kit(10test), 1928 Nos, 11-Feb-2021, 11-Feb-2023
4000024612, 96MB100-10, MBK G-6PD (Qualitative) Test Kit(10test), 148 Nos, 20-Jan-2021, 20-Jan-2023
Disease Status
4000024271, 16IC101-10, Crystal-VcC(Dipstick-10tests) Test Kit, 2428 Nos, 07-Nov-2020, 07-May-2022
4000024806, 55IC104-25, Parahit -F Ver. 1.0 Device (25 Tests), 7193 Nos, 03-Mar-2021, 03-Mar-2023
Immune Status
4000024830, 41LA300-20, ASO Latex Agglutination Test Kit (20tests), 4269 Nos., 05-Mar-2021, 05-Sep-2022
4000024714, 41LA300-20, ASO Latex Agglutination Test Kit (20tests), 944 Nos., 11-Feb-2021, 11-Aug-2022
Transmissible Agents
4000024521, 53FT201-50, Signal HCV Ver. 3.0 (50 Tests), 695 Nos, 02-Jan-2021, 02-Jan-2023
4000024705, 54FT200-60, RPR Antigen Test Kit (100 Tests), 896 Nos., 10-Feb-2021, 10-Aug-2022
Microbiology
4000024429, 18LM005-05, Tuberculin PPD/5TU/0.1ml (5ml), 3739 Nos., 15-Dec-2020, 15-Mar-2022
4000024843, 17TA417-50, Febrile S.Typhi Ag Set H,O,A(H)&B(H), 344 Nos., 08-Mar-2021, 22-Mar-2021
Serology Tests
4000024552, 54FT300-50, Trust Antigen Test Kit, 614 Nos., 07-Jan-2021, 07-Jul-2022
4000024641, 41LA200-20, CRP Latex Agglutination Test Kit (20tests), 6295 Nos., 27-Jan-2021, 27-Jul-2022

Production Processes witnessed:

- Manufacturing: 200000198 Urea Standards 50mg/dl 2ml, Batch No. 3000065899, 500 Nos., MFG 02-Apr-2021, Expiry 02-Jan-2023

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- Manufacturing: 52IC102-25 Immunochromatographic one step Rapid Visual Test for Hepatitis-B Surface Antigen Device: Crystal HBsAg, Batch No. 4000024949, 1800 Nos., MFG 30-Mar-2021, Expiry 30-Dec-2022
- Packing: 11AS128-10 Anti-B Monoclonal : Spanclone, Batch No. 4000024970, 1510 Nos, MFG 03-Apr-2021, Expiry 03-Apr-2022

Components sampled:
- Material Code, Material Description, Quantity, Batch No.

Urea Standards 50mg/dl 2ml
- 100000095, Benzoic Acid LR, 2.5gm, 1000043185
- 100000333, Urea AR, 0.625gm, 1000043370
- 100001351, Purified Water, 1.25Lit., 1000044101
- 700000014, Vial Glass 2ml (13mm) S/N USP-1 Amber, 500 Nos.
- 700000102, Plug Plastic (13mm) LDPE No.0, 500 Nos.
- 700000108, Cap Plastic (13mm) Plain Black, 500 Nos.

Crystal HbsAg
- 100000422, Polyclonal Anti-HbsAG (Equine)(for NCM), 14.544mg, 1000044089
- 100000520, Absorbent Pad 30mmX500ft, Grade 222, 292 Nos., 1000042269
- 100000526, Conjugate Releasing Pad 10mm Grade 6618, 576ft, 1000043562
- 100001851, Absorbent Pad – CF6: 22mmX50Mtr, 587 Nos., 1000043333
- 100003011, Goat Anti-IgY (Chicken IgY) Antibody, 13.500mg, 1000041343
- 100003862, Nitrocellulose Membrane PD31, 172.52m, 1000042874S

Testing witnessed:
Urea Standards 50mg/dl 2ml: Inprocess Inspection after bulk preparation (before filtration and filling)
Crystal HbsAg: Second Stage Inprocess Inspection(before start of automation of device assembly)

Sampling was conducted on 25 of approximately 100s production records/DHRs generated since the previous audit.

The production processes are defined for both sub-assemblies and end-products. In-process and final testing are conducted. Production areas are clean and well-kept and all staff demonstrated familiarity followed the established procedures. Records are maintained of the builds. Overall, the production processes are effective and meets the audit criteria.

Non-Conformities Issued:

☒ None **☐ AR#:** **Clause Reference**

Process **Customer Requirements Process**
Clauses Assessed **7.2.1, 7.2.2, 7.2.3a,b**
Area Visited Sales/Marketing
Person(s) Interviewed
Hemal Naik—assistant manager

Process Documents Assessed:
SOP for customer processes and customer communication, DP/09, Ver. 06, date 02-07-2018

Discussion of Findings
Customer requirements are determined for delivery and post-delivery activities as well as any user training. The quotes/orders do include records of amendments and changes. The manufacturer is

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selling approved medical devices in jurisdictions where they have approval. The official languages for the jurisdictions are also taken into consideration.

There was evidence that the organization has implemented marketing authorization controls.

The manufacturer is selling only approved medical devices in the EU. The official languages for the EU are also taken into consideration.

Records sampled:
Sales orders/quotes records:
Instruments:

Customer Name & Place	Category	PO & Date	Item name	Qty
Nidan Diagnostics Clinical Laboratory - Gondia	Direct	Email:- 06-02-2021	Autochem Xact Pro	1
Vigyan Bhavan - Ballia	Distributor	Email:- 29-01-2021	AUTOCHEM INGENIIOUS - OUTRIGHT SALE	1
Rafa Laboratores - Vijaywada	Direct	Email:- 17-12-2020	AUTOCHEM INGENIIOUS - OUTRIGHT SALE	1
Bala Enterprise - Karaikudi	Distributor	Email:- 26-11-2020	AUTOCHEM INGENIIOUS - OUTRIGHT SALE	1
Kritartha Traders - Guwahati	Distributor	Email:- 04-11-2020	THROMBOSTAT	1
Ravi Poly Clinic And Laboratory - Vemagal	Direct	Email:- 21-10-2020	AUTOCELL PLUS	1
Priyanshu Enterprises - Ranchi	Distributor	Email:- 14-10-2020	AUTOCHEM INGENIIOUS - OUTRIGHT SALE	1
Symbio Scientific Private Limited - Delhi	Direct - institutional	PO-AHCL-01	U120 URINE ANALYSER (1 NOS.)	1
Spss Mediline - Delhi	Distributor-institutional	Email:- 13-01-2021	ADAMS A1c HA-8180V (IND) Set	1
Bhagwati Multispeciality Hospital - Nanded	Direct	Email:- 11-09-2020	Autochem Xact Pro	1
Shri Ram Pathology Lab - Meerut	Direct	Email:- 14-08-2020	THROMBOSTAT	1
Om Biotech - Varanassi	Distributor	Email:- 29-09-2020	AUTOCELL PLUS	1
Medisys - Guwahati	Distributor	Email:- 22-06-2020	THROMBOSTAT	1

Reagents:

Customer Name & Place	Category	PO & Date	Item name	Qty
Udani Diagnostics Service - Kolkata	Distributor	Email - 17.03.2021	ASO LATEX AGGLUTINATION TEST KIT(20TEST)	150
Speciality Diagnostics	Distributor	Email - 08.03.2021	TUBERCULIN PPD 5TU/0.1ML (5ML)	15

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Agencies - Cochin				
Eastern Scientific Emporium - Gorakhpur	Distributor	143	WIDAL S.TYPHI AG SET H,O,A(H)&B(H)4X5ML	100
S.R.Diagnostics Pvt.Ltd. - Meerut	Distributor	SRDPL/01080/20-21	CRP LATEX AGGLUTINATION TEST KIT(20TEST)	100
Bindesh Corporation - Banglore	Distributor	BC-PO-165	LG TRIGLYCERIDES TEST KIT(2X50ML)GPO/TRI	8
Dhruvi Diagnostics - Surat	Distributor	Email:-05.01.2021	AUTOSPAN GLUCOSE TEST KIT(10X100ML)GO/PO	7
Ragavi Diagnostic - Erode	Distributor	Email:-26.12.2020	RF LATEX AGGLUTINATION TEST KIT(20TESTS)	5
Diagnostic Sales House - Amritsar	Distributor	Email:-03.12.2020	SIGNAL HIV 3DSIGNAL HIV 3D VER 1.0 (50TESTS) TEST KIT(50TESTS) TEST KIT	8
Saurabh Enterprises - Agra	Distributor	Email:-27.11.2020	LG a-AMYLASE TEST KIT (10ML) CNPG3	25
Gyan Enterprises - Lucknow	Distributor	POGE22/20-21	AUTOSPAN ALP TEST KIT (10X5ML) PNPP	5
Gayatri Chemicals - Surat	Distributor	Email:-20.10.2020	HYDROCHLORIC ACID (N/10) (500ML)	20
J.D.Diagnostics Pvt.Ltd. - Cochin	Distributor	JD/279	TUBERCULIN PPD 2TU/0.1ML (5ML)	50
B.S.Medichem - Jabalpur	Distributor-Institutional	VEHICLE FACTORY JABALPUR/30-12-2020	SPANCLONE ANTI-A+B+D SERUM (3X10ML) MONO	290
Poorvi Diagnostics - Chandigarh	Distributor-Institutional	MH JAMMU/09-12-2020	SILVER HIGH PROFILE BLADE - (50 NOS)	6
Srinivasa X Ray And Allied Prod. - Nellore	Distributor-Institutional	GGH NELLORE/10-11-2020	AUTOSPAN TURBIGOLD CRP TEST KIT(50 ml)	5
Sree Sai Enterprises - Hyderabad	Distributor-Institutional	OSMANIA HOSPITAL/09-11-2020	WATER DEIONIZED (5L)	200

Process for preventing unauthorized shipments: Authorized and approved shipping and cargo agencies are used.
Distribution records:
Instruments:

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Lot / Batch Number	Dispatch date		Shipment Details	Delivery date
BU50619168	GI2021014835	2/9/2021	89198711-09.02.2021\SAFE EXPRESS	13.02.2021
4000024583	GI2021014312	1/29/2021	D64096536-30.01.2021\DTDC	03.02.2021
4000024451	GI2021012587	12/23/2020	50708710706-23.12.2020\BLUE DART	30.12.2020
4000023947	GI2021011574	11/30/2020	50703390835-30.11.2020\BLUE DART	07.12.2020
BK00625	GI2021010605	11/7/2020	D94888092-07.11.2020\DTDC	10.11.2020
BV2009067	GI2021009824	10/23/2020	180597535-23.10.2020\TCI EXPRESS	31.10.2020
4000023947	GI2021009228	10/15/2020	50703390404-15.10.2020\BLUE DART	21.10.2020
97K10007F3	GI2021015859	3/1/2021	D64125753-01.03.2021\DTDC	03.03.2021
12012003	MI2021019128	1/19/2021	50866658043-19.01.2021\BLUEDART	22.01.2021
BU50619164	GI2021006937	9/16/2021	180595785-16.09.2020\TCI EXPRESS	24.09.2020
BK00549	GI2021005313	8/21/2020	D93715589-21.08.2020\DTDC	27.08.2020
BV2001014	GI2021008381	10/1/2020	50703027745-01.10.2020\BLUE DART	07.10.2020
BK00548	GI2021002453	6/22/2020	58299417190-22.06.2020\BLUE DART	01.07.2020

Reagents:

Lot / Batch Number	Dispatch date		Shipment Details	Delivery date
4000024830	GI2021016751	18.03.2021	DTDC-D64756655/18-03-2021	20.03.2021
4000024429	GI2021016294	09.03.2021	DTDC-D64756551/09-03-2021	11.03.2021
4000024008	GI2021015324	18.02.2021	DTDC-D64125578/18-02-2021	22.02.2021
4000024526	GI2021014847	09.02.2021	BLUEDART-50723720994/09-02-2021	12.02.2021
4000024350	GI2021013466	13.01.2021	DTDC-D62806734/13-02-2021	15.01.2021
4000024091	GI2021013211	06.01.2021	NANDAN Courier-1996200080520/06-01-2021	07.01.2021
4000024259	GI2021012763	28.12.2020	BLUEDART-58234407851/28-12-2020	30.12.2020

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4000024132	GI20210117 26	04.12.20 20	BLUEDART-58234406576/04-12-2020	09.12.2020
4000024066	GI20210114 30	28.11.20 20	DTDC-D62009890/28-11-2020	30.11.2020
4000024221	GI20210106 94	09.11.20 20	DTDC-D94888107/09-11-2020	12.11.2020
4000023915	GI20210095 93	21.10.20 20	NANDAN Courier-Hand Delivery/21-10-2020	23.10.2020
4000023389	GI20210086 86	06.10.20 20	DTDC-D94858351/06-10-2020	07.10.2020
4000024275	GI20210129 39	31.12.20 20	MARUTI -20204200217202/31-12-2020	02.01.2021
041420RHP	GI20210120 22	10.12.20 20	DTDC-D61515625/10-12-2020	12.12.2020
4000024230	GI20210107 54	11.11.20 20	DTDC-D94888120/11-11-2020	16.11.2020
4000024135	GI20210107 14	10.11.20 20	VTRANS-25013406/10-11-2020	13.11.2020

Marketing Authorization Responsible personnel: Mr. Hemal Naik and Mr. Mitesh Naik
Training records:
Inhouse training on internal auditor for ISO 9001:2015 , ISO 13485:2016, 98/79/EEC directive, date of training 24-06-2019 and 25-06-2019

Sampling was conducted on 29 of approximately 100s sales orders/quotes generated since the previous audit.

The order process is defined and meets the requirements. The customer requirements process is in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process **Purchasing Process; Outsourcing**
Clauses Assessed **7.4.1, 7.4.2; 4.1.5**
Area Visited Purchasing
Person(s) Interviewed
Keyur Pandya--- Executive purchase

Process Documents Assessed:
SOP for purchasing and control of outsourced process, DP/11, Ver. 06, date 02-07-2018

Discussion of Findings
There is a documented purchasing procedure. Non-fulfilment of purchasing requirements is addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. There is an established criteria for the selection, evaluation, monitoring and re-evaluation of suppliers which is proportionate to the risk associated with the medical device.

Purchasing requirements for products and services that suppliers are defined and communicated. Necessary risk control measures are defined. Purchasing information does include an agreement that

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the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. Purchase orders are generated and include all necessary information to obtain qualified parts and provide traceability.

The organization does have control of its outsourced processes. There was evidence of controls within the quality management system and proper documentation was verified.

Records sampled:
Suppliers evaluation records:
Major criteria for evaluation:
Price –no. of lots delivered on time—no. of lots delivered late-- no. of lots ok-- no. of lots fail-- no. of lots accepted under deviation---

- Advanced micro devices (P) Ltd., period of evaluation 2020-21 H2—68%, date of evaluation 01-10-2020
- Roche diagnostics India Pvt, Ltd., period of evaluation 2020-21 H2—75.5%, date of evaluation 01-10-2020
- Sigma Aldrich Chemicala Private limited, period of evaluation 2020-21 H2—82%, date of evaluation 01-10-2020
- DK Enzymes and chemicals, period of evaluation 2020-21 H2—68%, date of evaluation 01-10-2020
- Lonza India Pvt. Ltd., period of evaluation 2020-21 H2—76%, date of evaluation 01-10-2020
- Auracare Pharma and Biotech, period of evaluation 2020-21 H2—100%, date of evaluation 01-10-2020
- Jyoti Plastic works Pvt. Ltd., period of evaluation 2020-21 H2—66%, date of evaluation 01-10-2020
- Qualisure scientific LLC, period of evaluation 2020-21 H2—65.5%, date of evaluation 01-10-2020
- National bioproducts Institute, period of evaluation 2020-21 H2—76%, date of evaluation 01-10-2020
- Fapon International Ltd., period of evaluation 2020-21 H2—76%, date of evaluation 01-10-2020
- Vista Laboratories services, period of evaluation 2020-21 H2—100%, date of evaluation 01-10-2020

Purchasing requirements:
Material code, description, quantity, terms and conditions

PO records sampled:

- PO No. 4500066649, date 16-12-2020
- PO No. 4500067454, date 18-02-2021
- PO No. 4500067410, date 17-02-2021
- PO No. 4500067742, date 18-03-2021
- PO No. 4500067457, date 18-02-2021
- PO No. 4500067848, date 30-03-2021
- PO No. 4600007548, date 14-10-2020
- PO No. 4600007620, date 28-11-2020
- PO No. 4500066435, date 28-11-2020
- PO No. 4600007602, date 13-11-2020
- PO No. 4500067753, date 18-03-2021
- PO No. 4500067837, date 30-03-2021
- PO No. 4500067757, date 18-03-2021
- PO No. 4600007722, date 17-02-2021

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Sampling was conducted on 11 of approximately 100s suppliers.

The supplier control process is defined. The re-evaluation process is defined. Controls for the suppliers are based on risk of the material provided. Purchasing is controlled through a materials requisition system and purchasing is limited to the approved suppliers in the system. The purchasing process is in conformity with the audit criteria.

Non-Conformities Issued:

☒ **None** ☐ **AR#:** **Clause Reference**

Proess **Receiving, Preservation of Product, Identification/Traceability, Processes**
Clauses Assessed **7.4.3, 7.5.11, 7.5.8, 7.5.9.1**
Area Visited Receiving, Incoming Inspection, Shipping, Warehouse
Person(s) Interviewed
Manish Desai –Assistant manager QA
Bhavin Mistry---Assistant manager QA

Process Documents Assessed:
DP/22, Ver.07, 07-Apr-2018 Standard for Monitoring & Measurement of product (Inspection and Testing)
DP/15, Ver.06, 02-Jul-2018 Standard for Identification Traceability and Status
DP/17, Ver.07, 04-Jan-2021 Standard for Preservation of Products

Discussion of Findings
There is a process established and implemented for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities is based on the supplier evaluation results and proportionate to the risks associated with the purchased product. Method of inspection, test and tools identified does satisfy the intended parameters to be verified. When changes to the purchased product are identified, these changes are evaluated to determine if they affect the product realization process or the medical device.

There is a documented procedure for preserving the conformity of product. This preservation of materials, in-process and finished products does include designing and constructing suitable packaging and shipping containers. There are documented requirements for special conditions needed if packaging alone cannot provide preservation which includes controlling and recording special conditions.

There is a documented procedure to identify product by suitable means throughout product realization. Identification of product status is maintained throughout production, storage, installation and servicing of product that has passed the required inspections and tests or released under an authorized concession. There is a documented system to assign unique device identification (UDI). When medical devices returned they are identified and distinguished from conforming product.

There is a documented procedure for traceability. This procedure does define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained. Transport and storage requirements do match the defined instructions. The device labelling did meet the country specific requirements. The labelling did include the proper device identifiers per class of device and accompanies device throughout distribution. The IFU and labelling is provided in the appropriate country specific language.

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The materials used to Test IVDs are stored in a controlled manner and are also identifiable and traceable to higher level reference materials. The CE Mark with the identifying number on the device(s) is in compliance with IVDD Article 16 and Annex X.

Records sampled:
Incoming inspection records sampled:

- AR No. 1-43010, date 15-12-2020, Recombinant Antigen, Catalog no. GRJHIVS202, Lot no. 20190829
- AR No. 1-43008, date 15-12-2020, Recombinant Antigen, Catalog no. GRCHIVS203, Lot no. 20190919
- AR No. 1-43262, date 08-01-2021, Recombinant Antigen, Catalog no. GRJHIVS202, Lot no. 20190829
- AR No. 100004333, date 02-01-2021, Mouse monoclonal antibody (IgM), product code PTL-3, batch no. PTL-3-066
- AR No. 100004333, date 02-01-2021, Mouse monoclonal antibody (IgG1), product code C1-13, batch no. C1-13-060
- AR no. 1000043475, date 19-01-2021, Methyl celulose (Sigma), code- 00100004036, lot no. SLCC9072
- AR no. 1000043531, date 29-01-2021, Nitrocellulose membrane laminated plastics sheet, code: 00100002161, lot no. 10000685068
- AR No. 1000043718, date 18-02-2021, L-Glutamin, code: 00100001000, lot no. 10000688360
- AR No. 1000043770, date 18-02-2021, Mouse monoclonal antibody (IgG1), product code C1-13, batch no. C1-13-061
- AR 1000043930, date 08-03-2021, L-Glycerol, code:000100000414, batch no. 10000691795

Sampling plan methods: As per sampling plan SQ/MD/G 10.36

Transport and storage records:
Material Code: 84LS100-60, Name: LG ALBUMIN TEST KIT (100ML) BCG, Batch No. 4000024793, Storage: Room Temperature

Material Code: 55IC203-50, Name: PARAHIT TOTAL VER. 1.0 (DIPSTICK-50TEST), Batch N0. 4000024204, Storage: Room Temperature

Material Code: 57FT100-05, Name: SIGNAL MF (5TESTS) TESTKIT, Batch No. 4000024758, Storage: Room Temperature

Material Code: 71LS200-40, Name: LG CHOLESTEROL TEST KIT (2X20ML)CHOD-PAP, Batch No. 4000024863, Storage: 2 - 8 degree celcius

Sampling was conducted on 10 of approximately 100s incoming inspection records generated since the previous audit.

The receiving/incoming inspection process is defined. The preservation of product process is defined. The identification/traceability process is defined. These processes are in conformity with the audit criteria.

Non-Conformities Issued:

☒ **None**	☐ **AR#:**	**Clause Reference**

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Process **Receiving, Preservation of Product, Identification/Traceability, Processes - Site 2-1 Warehouse**
Clauses Assessed **7.4.3, 7.5.11, 7.5.8, 7.5.9.1**
Area Visited Receiving, Incoming Inspection, Shipping, Warehouse
Person(s) Interviewed
Mr. Bankim Desai, Branch Manager - Warehouse

Process Documents Assessed:
DP/22, Ver.07, 07-Apr-2018 Standard for Monitoring & Measurement of product (Inspection and Testing)
DP/15, Ver.06, 02-Jul-2018 Standard for Identification Traceability and Status
DP/17, Ver.07, 04-Jan-2021 Standard for Preservation of Products

Discussion of Findings
There is a process established and implemented for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities is based on the supplier evaluation results and proportionate to the risks associated with the purchased product. Method of inspection, test and tools identified does satisfy the intended parameters to be verified. When changes to the purchased product are identified, these changes are evaluated to determine if they affect the product realization process or the medical device.

There is a documented procedure for preserving the conformity of product. This preservation of materials, in-process and finished products does include designing and constructing suitable packaging and shipping containers. There are documented requirements for special conditions needed if packaging alone cannot provide preservation which includes controlling and recording special conditions.

There is a documented procedure to identify product by suitable means throughout product realization. Identification of product status is maintained throughout production, storage, installation and servicing of product that has passed the required inspections and tests or released under an authorized concession. There is a documented system to assign unique device identification (UDI). When medical devices returned they are identified and distinguished from conforming product.

There is a documented procedure for traceability. This procedure does define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained. Transport and storage requirements do match the defined instructions. The device labelling did meet the country specific requirements. The labelling did include the proper device identifiers per class of device and accompanies device throughout distribution. The IFU and labelling is provided in the appropriate country specific language.

The CE Mark with the identifying number on the device(s) is in compliance with IVDD Article 16 and Annex X.

Records sampled:
Site 2-1 Warehouse

Incoming inspection records sampled:

GRN No.	Product ID	Product Name	Quantity Received	Accepted	Date
5000214266	93GS998-50	Glucocard G Test Strips 50s	673	673	03-Mar-2021
5000214338	18LM002-05	Tuberculin Ppd 2 Tu	100	100	04-Mar-2021
5000214340	00300008283	Orinasys Gk	35	35	04-Mar-2021
5000214665	29FA110-11	Glucocard Sigma Meter	199	199	12-Mar-2021
5000214754	53FT201-50	Signal Hcv Ver 3.0 (50 Tests)	10	10	15-Mar-2021
5000214784	93GS102-50	Glucocard Sigma Test Strips	9784	9784	16-Mar-2021

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5000214785	A78518	Gc 01 100s	1490	1490	16-Mar-2021
5000215077	93GS999-60	Glucocard Vital Test Strip (Blister Pack))	3432	3432	24-Mar-2021
5000215140	17SA428-05	Widal S.Typhi Ag Set H,O,A(H)&B(H)4x5ml	20	20	26-Mar-2021
5000215211	93GS998-25	Glucocard G+ Test Strips (25s Al)	746	746	27-Mar-2021

Storage, Location, Condition and Expiry

Material Description	Material No	Batch	Quantity	Date of Expiry
Storage Location(Num): 1140	Storage Location: FT- Room Temp			
Orinasys B 10 - 100 Nos.	000030000823	URS9040041	107.000	31-Oct-2021
Lyse For Autocell Plus (1L)	000030001835	31211-044	2.000	30-Sep-2022
Storage Location(Num): 1040	Storage Location: FG-RT/Domestic			
Parahit Total+ (Device-50t) With Pipette	55IC206-50	4000023608	11.000	03-Jul-2022
Field`S Stain-B (500ml)	24SS714-75	4000024020	10.000	26-Sep-2025
Drabkin`S Solution (1l)	23RR621-80	4000024294	5.000	13-Nov-2025
Lg Urea Test Kit (2x65ml) Ned-Dye	81LS200-61	4000024420	12.000	14-Dec-2022
Storage Location(Num): 1050,	Storage Location: FG 2-8°C			
Widal S.Typhi Ag Set H,O,A(H)&B(H)4x5ml	17SA428-05	4000024404	49.000	08-Jun-2022
Tuberculin Ppd 10tu/0.1ml (5ml)	18LM010-05	4000024431	236.00	15-Mar-2022
Lg Cholesterol Test Kit (2x20ml)Chod-Pap	71LS200-40	4000023985	14.000	19-Mar-2022
Mbk Alp Test Kit(20x2.2ml) Kind & King`S	75MB100-40	4000024703	5.000	09-Feb-2023
Lg Uric Acid Test Kit (2x10ml) Uri/Tri	82LS200-20	4000024681	10.000	03-Feb-2022
Autospan Glucose Test Kit(10x100ml)Go/Po	93DP100-80	4000024441	5.000	16-Jun-2022

Sampling was conducted on 10 of approximately 100s incoming inspection records generated since the previous audit.

The receiving/incoming inspection process is defined. The preservation of product process is defined. The identification/traceability process is defined. These processes are in conformity with the audit criteria.

Non-Conformities Issued:

☒ **None** ☐ **AR#:** **Clause Reference**

Process **Control of Non-Conforming Product Process**
Clauses Assessed **8.3.1, 8.3.2, 8.3.4**
Area Visited Non-Conforming Materials
Person(s) Interviewed
Bhavin Mistry—Assistant manager QA

Process Documents Assessed:
SOP for non-conforming product control, DP/23, Ver. 11, date 16-05-2020

Discussion of Findings
There is a documented procedure to define the controls of nonconforming product, including dissemination of information. The non-conforming product is segregated. The evaluation of nonconformities does include a determination of the need for an investigation and notification of any

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external party responsible for the nonconformity. Records of the nonconformities, actions, and the rationale for decisions are maintained.

All non-conforming material is evaluated, or its use authorized for release or acceptance under concession. The nonconforming product is accepted by concession only if the justification is provided, approval is obtained, and applicable regulatory requirements are met, including the identity of the person authorizing the concession.

Rework is conducted in accordance with documented procedures. These procedures are reviewed and approved. After the completion of rework, the product is verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records sampled:
Method of Segregation: colored bin, tags, quarantine in designated areas.

NCR records sampled:
- AMICA-2020-002, date 29-08-2020
- AMICA-2020-003, date 26-10-2020
- AMICA-2020-004, date 08-12-2020
- AMICA-2020-005, date 09-12-2020
- AMICA-2020-006, date 25-12-2020

Sampling was conducted on 6 of approximately 6 NCR records generated since the previous audit.

The non-conforming product process is defined and being tracked and trended. Records are maintained and reviewed. The non-conforming product process is in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process	**Infrastructure, Work Environment/Contamination Control, Calibration Processes – CL & Site 2-1 Warehouse**
Clauses Assessed	**6.3, 6.4.1, 6.4.2, 7.6**
Area Visited	Maintenance, Work Environment and Contamination Control, Calibration

Person(s) Interviewed
Mr. Devanshu Desai, Manager – QA
Mr. Bhavin Mistry, Asst Manager – QA
Mr. Dipen Patel, Manager - Equipment & Facility (Maintenance)
Mr. Vipul Naik, Deputy Manager – Production (Work Environment and Contamination Control)
Mr. Hemal Naik, Asst Manager - QC Inst. (Calibration)
Mr. Bankim Desai, Branch Manager - Warehouse

Process Documents Assessed:
DP/06, Ver.08, 02-Jul-2018 Standard for Preventive and Breakdown Maintenance of Equipment
DP/07, Ver.06, 02-Jul-2018 Standard for Work Environment (Including Health, Cleanliness, Clothing and Contamination Control)
SM/S/012, Ver.13, 09-Mar-2020 Procedure for Environmental Monitoring (A)
DP/18, Ver.08, 25-Mar-2021 Standard for Control of Monitoring & Measuring Devices
SOPs for Internal Calibration
PP/S/019, Rev.4, 05-Nov-2019 Micro pipette variable Thermo
PP/S/018, Rev.6 , 26-Feb-2020 pH indicator / controller Bela Inst. Model : 672 P
SM/S/002, Ver.14, 13-Jan-2020 Procedure for Preventive Maintenance of Machines and Utilities

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SM/S/001 Rev 09, 13-Jan-2020 Procedure for breakdown maintenance of machines and utilities
SM/S/010, Ver.09, 04-Jun-2018 Procedure for Calibration of Monitoring & Measuring Equipment
SM/S/012, Ver.13, 09-Mar-2020 Procedure for Environmental Monitoring (A)
PS/S/056, Ver.05 Procedure for Monitoring of Non-viable Particle count using Fluke 985 Particle Counter
PV/S/007 Rev 03 Dated 19-Feb-2021 – Procedure for ESD control
SQ/S/117, Ver.08, dated 01-Jun-2019 Procedure for Settling Plate Count of Sterile Room and Low Bio-burden Area of Production and Quality Control.

Discussion of Findings
There are documented requirements to identify the infrastructure of the site. Maintenance activities are documented and do include the interval of performing the maintenance activities. These requirements do apply to equipment used in production, the control of the work environment and monitoring and measurement and records for maintenance are maintained.

There are documented requirements for the work environment. This does include documented requirements to monitor and control the work environment. There is a defined process for handling ESD sensitive components. Records were available for review.

There are documented requirements for health, cleanliness and clothing of personnel. This does include personnel who are required to work temporarily under special environmental conditions. There are documented arrangements for the control of contaminated or potentially contaminated product.

There is a documented procedure for monitoring and measurement. Equipment requiring calibration is scheduled and records are maintained. Records for calibration were traceable to approved vendors that performed the calibration and each certificate was traceable to Nationally recognized standards (i.e NIST). Internal calibration records did provide sufficient documentation to trace calibrations back to calibrated equipment in accordance with documented procedures. The measuring equipment does have identification. If the measuring equipment is adjusted or re-adjusted, such adjustments were recorded. If equipment was found to be out of tolerance, there is a defined process for reviewing the effect on previous product.

When computer software is used for the monitoring and measurement there are documented procedures for the validation. The validations did occur prior to initial use and after changes. The software validation and revalidation was proportionate to the risk associated with the use of the software.

There are documented requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

The cleanroom has been validated according to the ISO14644-1 requirements. The limit values are defined in the procedure. The control of initial contamination is documented in the bioburden records. The monitoring of the cleanroom and calibration of the instruments used are documented. The personal working in the cleanroom have been trained and the information about the gowning and de-gowning process was available. The requirements about the personal hygiene are defined and monitored.

Records sampled:
Preventive maintenance records sampled:
SM/F/123 Equipment Preventive Maintenance Report
Equipment Id_ Equipment Name – Order No. – Date
1000000000118_Bio Safety Cabinet – 50039395 – 16-Oct-2020
1000000000141_Gulitine Cutter – 50039801 – 22-Dec-2020
1000000000149_ISO flow – 50039665 – 09-Feb-2021

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1000000000180_AHU DH#7 – 50039689 – 05-Feb-2021
1000000000181_AHU DH#8 – 50039693 – 04-Feb-2021
1000000000192_Oven – 50039407 – 07-Jan-2021
1000000000222_Cont.Band Sealer – 50039713 -18-Feb-2021
1000000000540_Sticker labeling – 50039577 – 07-Jan-2021
1000000000567_Semi Auto Sealer – 50039457 – 27-Nov-2020
1000000000665_LAF – 50039479 – 18-Sep-2020

ESD Controls and Records: Daily Monitoring Records
SV/F/215, Rev. 00, Work Sheet for ESD Checking Quality Control (Instrument) – Verified for 22-Mar to 31-Mar-2021
Work Stations: WS#1 (Electronics Assembly), WS#2 (Electronics Assembly), WS#3(Mechanical Assembly), WS#4 (Final Assembly), WS#5 (Incoming Inspection Work Station) and WS#6 (PCB Inspection Work Station)
Parameters Verified
ESD Mat, Wrist Strap, Wrist Strap Cable – Satisfactory
ESD Wrist Selt Test – PASS
ESD Mat to Ground Point – 0-20Ω
Phase & Earth Point – 210-240 VAC
Neutral and Earth Point – 0-5 VAC

Calibration records sampled:

Name of MME, New MME No., Tag No., Calibration Certificate/Report Ref., Date

External Calibration at R.G.Technologies, Frequency - Annually
Shrink Machine (PC/E/2/07/026)
Temp. Controller, 2000000000008, PC/T/FX/017, RGT/H-237/20-21 dated 24-Nov-2020
Temp. Sensor, 2000000000009, PC/T/FX/017A, RGT/H-238/20-21 dated 24-Nov-2020
Temp. Controller, 2000000000010,PC/T/FX/018, RGT/H-239/20-21 dated 24-Nov-2020
Temp. Sensor, 2000000000011, PC/T/FX/018A, RGT/H-240/20-21 dated 24-Nov-2020

Bio Safety Cabinet (PI/E/3/24/297)
Magnehelic Gauge, 2000000000086, PI/P/FX/039, RGT/C-863/20-21 dated 26-Jun-2020
Magnehelic Gauge, 2000000000089, PI/P/FX/041, RGT/C-864/20-21 dated 26-Jun-2020

Magnehelic Gauge (LFT DH-7), 2000000000137, PI/P/FX/185, RGT/H-271/20-21 dated 24-Nov-2020,

Magnehelic Gauge (LFT Air lock - LFT P. Room-1 to DH-8, 0736/B), 2000000000141,PI/P/FX/189, RGT/H-275/20-21 dated 24-Nov-2020

Digital Weighing Balance (Raw Materials Disp. Room-2 W/H), 2000000000580, SW/W/PR/034, RGT/J-234/20-21 dated 06-Jan-2021

Weighing Balance, 2000000001074, 2000000001074, RGT/A-126/20-21 dated 17-Apr-2020

Internal Calibration: Frquency: 6 months
Format: CALIB/MME/SQ/2015/001 Calibration Certificate of Monitoring and Measuring Equipment (MME)

YSI 2300 STAT Plus (To measure Glucose Concentration in Plasma), 2000000001000, 2000000001000, CALIB/MME/SQ/2021/016 dated 18-Jan-2021

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ABL 80 Flex (To measure O2 Concentration in Plasma) , 2000000001001, 2000000001001, CALIB/MME/SQ/2021/017 dated 18-Jan-2021

Micro Pipette, 2000000001140, 2000000001140 CALIB/MME/PM/2021/008 dated 28-Dec-2020

Digital pH meter (Compounding Room – 0739/B), 2000000000212, PI/R/PR/274, CALIB/MME/PI/2021/068 dated 23-Feb-2021
Masters Used: Certificate of Analysis from Hanna Instruments
Product Code – Lot No. – Mean Lot Value – Expiry
HI6091 – 9897 – 9.180±0.002@25°C – Mar-2021
HI6007 – 0878 – 7.014±0.002@25°C – Dec-2021
HI6016 – 0260 – 1.680±0.002@25°C – Jun-2021
HI6124 – 9897 – 12.454±0.002@25°C – Jul-2021
HI6004 – 0655 – 4.008±0.002@25°C – Oct-2021

Work environment conditions records (include ESD):
Frequency & Limits for Temperature monitored through Electronic Data Monitoring System is as follow:

#	Area	Temperature Range	Frequency of Monitoring
1	Cold Rooms	+2º C to +8º C	Every 60 minutes
2	Deep Freeze	-16°C to -24°C	Every 30 minutes
3	Ultra Low Freeze	-60°C to -80°C	Every 30 minutes
4	Air Conditioned Area	+20ºC to +30ºC	Every 120 minutes
5	Incubator Room	+35ºC to +39ºC & +43ºC to +47ºC	Every 4 hours

Humidity Controlled Area : (Humidity Range : ≤ 25% RH)
Refrigerators (Temperature range: +2o C to +8o C)
Differential Pressure Monitoring
Bio Burden Monitoring SOP No. SQ/S/117 of QA
Non-viable Particle Count Monitoring SOP No. PS/S/056 of PS
Reviewed the Humidity & Temperature monitoring for the month of Feb & Mar-2021
- Production - Biochemistry Section - DH 3 & DH 4
- Production - Immunology Section - DH 7 & DH 8

Reviewed Temperature monitoring for the month of Feb & Mar-2021
- Pl. Cold Room
- PS Cold Room

Cleanroom validation records sampled:
Velocity Measurement, Air Change Calculation, PAO, Particle Counting and Temperature Mapping
Filling Room-2 (710) – ISO Class 7
- RGT/A-0016/20-21 dated 22-Apr-2020 for PAO (DOP)
- RGT/A-0002/20-21 dated 22-Apr-2020 for Air Velocity, Air Volume and No. of Air Changes
- RGT/A-0034/20-21 dated 23-Apr-2020 for Particle Counting
- RGT/A-0053/20-21 dated 25-Apr-2021 for Temperature Mapping

Assembly Room (718) – ISO Class 8
- RGT/A-0017/20-21 dated 22-Apr-2020 for PAO (DOP)
- RGT/A-0003/20-21 dated 22-Apr-2020 for Air Velocity, Air Volume and No. of Air Changes
- RGT/A-0063/20-21 dated 24-Apr-2020 for Particle Counting
- RGT/A-0046/20-21 dated 22-Apr-2021 for Temperature Mapping

Health/cleanliness/clothing/PPE requirements:
- General medical examination once in 6 months
- Clean rest rooms, hand washing facility along with soap, detergent, and hand drier
- Clothing for all : Full sleeves over-gown, powder free gloves and disposable masks in the production area.

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- Clothing for all personnel working in clean room (class 100 & 1000): Clean garments and secondary gowning facility.

Decontamination records:
Training records for special environmental conditions:
Date - Training Title – Trainer - No. of Participants - Effectiveness Check Date
Effectiveness Check Method: Visual Observation
08-Aug-2020 - Entry, Exit in low bioburden area & clean room - Naresh Navsariwala – 2 – 13-Aug-2020
09-Oct-2020 - Operation of airborne particle counter - N.D.Navsariwala – 2 – 16-Oct-2020
25-Nov-2020 - Sterilization process of low bioburden area - N.D.Navsariwala – 3 – 03-Dec-2020
08-Jan-2021 - Entry, Exit in low bioburden area & clean room - Naresh Navsariwala – 1 – 13-Jan-2021

Cleanroom Class: Filling Room – Class 7 and Assembly Room – Class 8
Bioburden records sampled: Daily Monitoring (all working days) witnesses for Jan-2021 and Feb-2021
SQ/F/021, Ver.13 Settling Plate Count Record (Ref. SOP No. SQ/S/117)

- Section I – Sterility & Microbiological Testing Lab of QC
- Section II – Production Loq Bio-burden Area

Site 2-1 Warehouse:
Calibration records sampled:
Name of MME, New MME No., Tag No., Calibration Certificate/Report Ref., Date
Deep Freezer, Calibration Agency: R G Technologies
Temp. indicator of DF, 2000000000880, BM/T/FX/1/03/002, RGT/C-6182/20-21 dated 04-Jun-2020
Temp. sensor of DF, 2000000000881, BM/T/FX/1/03/002A, RGT/C-6183/20-21 dated 04-Jun-2020

Cold Room (05-17-50-30-0A-A1), Calibration Agency: Lisaline Lifesciences Technologies Pvt Ltd
Temp. Indicator of Data Logger CR (Cobalt), 2000000000883, BM/T/FX/2/02/004, LLTPL-21/01-T039 dated 07-Jan-2021
Temp. Indicator of Data Logger RT (cobalt), 2000000000884, BM/T/FX/2/03/005, LLTPL-21/01-T040 dated 07-Jan-2021

Work Environment Monitoring:
Reviewed Cold Room (BM-E-1-03-002)Temperature monitoring for the month of Jan, Feb & Mar-2021, +2º C to +8º C
Reviewed Deep Freezer (BM-E-1-02-001)Temperature monitoring for the month of Jan, Feb & Mar-2021, 0 to -20ºC

Sampling was conducted on 10 of approximately 150 equipment requiring preventive maintenance and 18 approximately 900 equipment requiring calibration.

The infrastructure, calibration and work environment processes are effective. These processes are in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process	**Validation of Processes for Production and Service, Quality Management System Software Validation Processes – CL**
Clauses Assessed	**7.5.6, 4.1.6**
Area Visited	Quality / Engineering

Person(s) Interviewed
Mr. Devanshu Desai, Manager – QA
Mr. Hussain Hakim, Executive – PE, (Process and Software Validation)

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Process Documents Assessed:
DP/14, Ver.09, 25-Mar-2021 Standard for Validation of Processes

Discussion of Findings
There is a documented procedure for validation of processes for production and service, including outsourced processes. The process does contain defined criteria for review and approval of the processes, define equipment qualification (IQ, OQ, PQ) and qualification of personnel. The process does define specific methods, procedures and acceptance criteria, requirements for records, revalidation, including criteria for revalidation, and approval of changes to the processes. When appropriate, the process does contain statistical techniques with rationale for sample sizes.

There is a documented procedure for the validation of the application of computer software used in production and service provision. The validations did occur prior to initial use and after changes to such software or its application. The software validation and revalidation was proportionate to the risk associated with the use of the software.

There is a documented procedure for the validation of the application of computer software used in in the quality management system. The validations did occur prior to initial use and after changes to such software or its application. The software validation and revalidation was proportionate to the risk associated with the use of the software.

Records sampled:
Process validation records sampled:
Process Name, Validation Ref. No., Validation Date, Validation Due Date
Cleaning of Process Container, TR-CCP-B-PV-003, 25-Feb-2021, 24-Feb-2026
Viability Testing Process for manufacturing of Microbiological Products, TR-VTM-B-PV-001, 12-Jun-2020, 11-Jun-2025
AutoSpan Liquid Gold Cholesterol End Point Assay Manufacturing Process, TR-LGC-B-PV-001, 28-Jun-2020, Till any change in the procedure processes

Calibration software validation records sampled:
Software Name, Validation Ref. No., Validation Date, Validation Due Date
BT 1500, VSR/ARK/CSV/Automatic Analyzer/2020/00, 28-Nov-2020, When any change in Software
Bio-Rad Image Lab, VSR/ARK/CSV/Densitometer/2020/00, 28-Nov-2020, When any change in Software

Reviewed all 5 process validation records generated since the previous audit.

The process validation process is defined. Records are maintained. Revalidation criteria is established for the equipment. The process validation process is in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process	**Installation Activities, Servicing Activities, Customer Property Processes**
Clauses Assessed	**7.5.3, 7.5.4, 7.5.10**
Area Visited	Production-Servicing, Customer Service-Installation

Person(s) Interviewed
Vimal Naik--- Assistant manager Instruments

Process Documents Assessed:
SOP for Installation and servicing, DP/30, Ver. 06, date 02-07-2018

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Discussion of Findings
There are documented requirements for medical device installation and acceptance criteria for verification of installation. When outsourced, documented requirements for medical device installation and verification of installation are provided to the vendor.

There are documented procedures and reference materials, for performing servicing activities and verifying that product requirements are met. There is evidence that records of servicing activities are analyzed to determine if the information is to be handled as a complaint and as an input to the improvement process.

The organization has defined a process to ensure customer property is under control and segregated from conforming materials. If the property is lost or damaged, this is communicated to the customer. Patient information and confidential health information is treated as customer property.

Records sampled:
Installation: Internal
Installation records sampled:
- Service notification no. 300025945, date 02-02-2021, New Sahara Patho lab
- Service notification no. 300025931, date 16-02-2021, Civil hospital
- Service notification no. 300025675, date 15-10-2020, Resure pathology lab & imaging
- Service notification no. 300025710, date 25-11-2020, G one pathology laboratory
- Service notification no. 300025442, date 28-07-2020, Bhagwati multispecialty hospital
- Service notification no. 300025569, date 22-10-2020, AKMC Pathology laboratory
- Service notification no. 300025983, date 19-02-2021, Nidan Diag. clinical lab
- Service notification no. 300026046, date 10-03-2021, Bansal pathology centre
- Service notification no. 300025730, date 16-12-2020, Gupta Pathology
- Service notification no. 300025800, date 28-12-2020, Rafa Laboratories

Installation training records sampled:
- Training on operation and servicing of instruments, date of training 10-12-2017 to 16-12-2017, Mr. Nursufique Ahmed
- Applicability of Analyzers, date of training 24-02-2020 to 29-02-2020, Mr. Prashant Mani and Mr, Niladri Roy
- Training on Autochem Xact Pro (operation and servicing), date of training 18-06-2018 to 20-06-2018, participants 08 no.'s

Servicing: Internal
Servicing records sampled:
- Service notification no. 300026036, date 09-11-2020, closed on 09-11-2020—PM Visit
- Service notification no. 300025570, date 30-10-2020, closed on 30-10-2020—PM Visit
- Service notification no. 300025774, date 24-12-2020, closed on 24-12-2020—PM Visit
- Service notification no. 300025642, date 28-11-2020, closed on 28-11-2020—PM Visit
- Service notification no. 300025933, date 21-10-2020, closed on 21-10-2020—PM Visit
- Service notification no. 300025551, date 21-10-2020, closed on 21-10-2020—PM Visit
- Service notification no. 300025522, date 24-09-2020, closed on 24-09-2020—PM Visit and application
- Service notification no. 300025984, date 08-02-2021, closed on 09-02-2021—Breakdown and PM Visit
- Service notification no. 300025995, date 05-02-2021, closed on 05-02-2021—PM Visit
- Service notification no. 300025968, date 18-02-2021, closed on 18-02-2021—PM Visit

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Servicing training records sampled:

- Training on operation and servicing of Analyzers, date of training 08-06-2017 to 13-06-2017, Mr. Rajat Kumar
- Training on operation and servicing of Instruments, date of training 04-01-2021 to 09-01-2021, Mr. Pavan Sharma and Mr. Ali Azam
- Training on operation and servicing of Analyzers, date of training 30-09-2019 to 05-10-2019, Mr. Sri Nivasam and Mr. Atul Kumar

Sampling was conducted on 10 of approximately 10s installation records and 10 of approximately 100s servicing records generated since the previous audit.

The installation and service processes are effective. These processes are in conformity with the audit criteria.

Non-Conformities Issued:

☒ **None** ☐ **AR#:** **Clause Reference**

Process **Human Resources (Training) Process – CL & Site 2-1 Warehouse**
Clauses Assessed **6.2**
Area Visited Human Resources / Engineering
Person(s) Interviewed
Mr. Devanshu Desai, Manager – QA
Ms. Khushboo Patel, Executive – Human Resources
Mr. Bankim Desai, Branch Manager - Warehouse

Process Documents Assessed:
DP/05, Ver.06, 02-Jul-2018 Standard for Competence, awareness and training

Discussion of Findings
There are documented processes for establishing competence, providing needed training, and ensuring awareness of personnel. The effectiveness of the training is evaluated. Personnel responsible for implementing regulatory requirements do have evidence of training to, or experience with, the applicable regulations.

Records sampled:
Training records sampled:
Date, Title of Training, Trainer, No. of participants, Effectiveness checking method, Date
10-Jun-2020, Supervisory Skills, Manpower Handling , Material Handling Bhuvnesh Deshmukh, 1, Practical Assignment, 18-Jun-2020
27-Jun-2020, Preparation of BPCR, Vipul Naik, 1, Visual Inspection, 29-Jun-2020
22-Sep-2020, Work Environment , Housekeeping Requirements, Bhuvnesh Deshmuk, 3,Practical Assignment , 27-Sep-2020
04-Dec-2020, Knowledge of cGMP Compliance, Yogesh Patel , 1, Work Record, 11-Dec-2020
26-Dec-2020, CE Marking, Devanshu Desai , 8, Questionnaire , 26-Dec-2020
23-Jan-2021, Knowledge of Prohibition Act 1949 & Poison Act, Ganesh Kude , 8, Questionnaire, 23-Jan-2021
20-Mar-2021,Awareness on Work Environment, Vipul Naik, 16, Awareness Training, 20-Mar-.2021

Site 2-1 Warehouse:
Date, Title of Training, Trainer, No. of participants, Effectiveness checking method, Date
29-Dec-2020, E-Invoice and E-way Bill Generation, Bankim Desai, 3, Work Record, 30-Dec-2020

Sampling was conducted on 8 of 26 training records.

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The training process is defined. Records are maintained. The training process is in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process	**Control of Document and Records Processes – CL & Site 2-1 Warehouse**
Clauses Assessed	**4.2.4, 4.2.5**
Area Visited	Document and Record Control

Person(s) Interviewed
Mr. Devanshu Desai, Manager – QA
Mr. Bhavin Mistry, Asst Manager – QA
Mr. Bankim Desai, Branch Manager – Warehouse

Process Documents Assessed:
DP/01, Ver.15, 08-Mar-2021 Standard for Quality Document Control
DP/02, Ver.09, 08-Mar-2021 Standard for Quality Records Control
SS/F/036, Ver.02, 01-Jan-2018 Retention Time for Documents and Records

Discussion of Findings
There is a documented procedure for control of documents. This process does include review and the approval of documents. Relevant versions of applicable documents are available at points of use. Obsolete versions of documents are controlled. Documents of external origin are identified. Information on the website is reviewed and records of the review are maintained. Marketing materials are reviewed and are under version control. We verified that the most recent version did include standards and regulations under the scope of the QMS.

There is a documented procedure for the control of records. The methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements is defined. The retention time of quality records conforms to the longest defined regulatory requirement.

Records sampled:
External origin records sampled:
98/79/EC
IVD Regulation（EU）2017/746
2009/108/EC
2009/886/EC
BS EN ISO 20776-1: 2020
BS EN ISO 15223-1: 2016
BS IS ISO 15197 : 2015
BS EN ISO 14644-1:2015
BS EN ISO 23640:2015
EN 12322: 1999

Website/Marketing review records: www.arkray.co.in

Obsolete documents sampled:
QSM/AHPL – 01, Rev. 09, 22-Jan-2020, Quality Manual, Current Rev.10, 01-Mar-2021
DP/10, Ver.10, 25-Nov-2019 Standard for Design and Development, Current Ver.11, 01-Jul-2020
PV/S/007, Ver.02, 21-Feb-2018 – Procedure for ESD control, Current Ver.03,19-Feb-2021

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Required Regulatory Retention Time: At-least life time of the medical device but not less than retention period of any records or not lea than two years from the medical device release by the organization.
Defined lifetime of the device: Shelf life varies from reagent to reagent 10 months to 60 months based on the stability study
Defined Retention time: 5 years from manufacturing

Site 2-1 Warehouse:
External origin records sampled:
ISO 9001:2015
ISO 13485:2016
IMDR 2017

Sampling was conducted on 13 of approximately 40 external origin documents.

The document control system is effective at maintaining the QMS documentation in an easily accessible and organized manner. Records are maintained and are retrievable and legible. The document and records processes are in conformity with the audit criteria.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

Process **Quality Management System**
Clauses Assessed **4.1.1, 4.1.2, 4.1.3, 4.1.4**

Discussion of Findings
Based on the evidence recorded in this report, the manufacturer:

Has applied a risk based approach to the control of the appropriate processes needed for the quality management system.

Has determined criteria and methods needed to ensure that both the operation and control of these processes are effective; availability of resources; necessary actions implemented to achieve planned results and maintain the effectiveness of these processes; monitoring, measuring and analysis of these processes; and records maintained to demonstrate conformance to the applicable regulatory requirements.

Has provided sufficient evidence that changes made to the quality management system processes are evaluated for their impact on the quality management system, evaluated for their impact on the medical devices produced, and controlled in accordance with the requirements of the applicable regulatory requirements.

There is sufficient evidence to demonstrate that the quality management system does maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

The quality manual system is organized and covers all of the regulatory requirements within the scope.

Non-Conformities Issued:
☒ **None** ☐ **AR#:** **Clause Reference**

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Audit Summary

There were no deviations from the provided Agenda.
Good documentation and very good infrastructure are the main strengths of the organization.

Due to the circumstances surrounding the COVID-19 outbreak UL has enacted the guidelines set forth in IAF ID3 and TPS 62 for conducting audits remotely during Extraordinary Circumstances. UL LLC and UL Inc. have placed a restriction on all International travel and the US Government has also place restrictions on domestic travel. Therefore, this audit was conducted remotely using the following tools and methods: Skype/Dropbox. This was considered a live audit with active customer participation using these tools. Onsite visits will reconvene with the next audit with the consideration that there will be no more than 12 months between this audit and the next regularly scheduled audit. This means that the next audit must be scheduled on or before the end of March 2022. Additionally, the certificate can only be issued for 12 months, pending the next onsite audit. At that time, the certificate will be issued for the remainder of the full cycle.

There were no non-conformities issued in this assessment.

The UL Registered Firm Mark is being used correctly.
The United Kingdom Accreditation Service accreditation mark is being used correctly.
The CE Mark is being used correctly and the Notified Body number is included.

Audit Conclusions

The audit was successful in meeting its stated objectives, and the results can be considered reliable. The results of the audit indicate that the client is in conformity with the audit criteria. The auditing of this QMS is based on a sampling process of the available information provided.

Overall, the quality management system is effectively implemented and the scope of certification is appropriate. There were no events evidenced during the audit that would reduce the reliability of this audit. The nonconformities issued were non systemic and do not indicate a degradation of the QMS. All objectives of the audit agenda and criteria were met and Arkray Healthcare Pvt Ltd has shown conformity to the requirements of ISO 13485:2016, the In-Vitro Diagnostic Devices Directive (pending successful completion of the technical file).

Recommendations

The UL audit team is pleased to recommend recertification for the following programs.
ISO 13485:2016
The In-Vitro Diagnostic Devices Directive (pending successful completion of the technical file)

The number of days for the next audit is 6.5 and will be your First Annual Audit.

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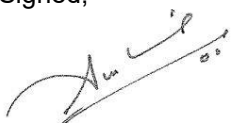
Identification

As lead auditor, I declare that the above report is a true and accurate representation of the audit. This is audit report version A and was provided to the Management Representative on 2021-05-25.

Signed,



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