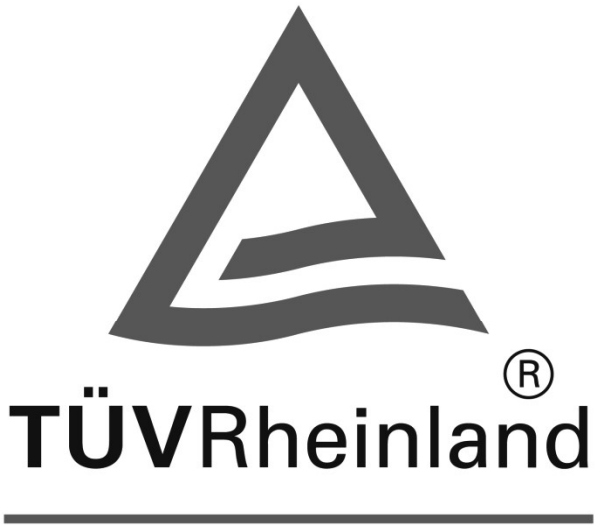

Audit Report

for

Yangzhou Medline Industry Co., Ltd.

No. 108, Jinshan Road, Economic Development Zone, Yangzhou, 225009 Jiangsu, P.R. China

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1. Audit conclusion

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

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

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

Procedures describing responsibilities for identifying failures and nonconformities were implemented. Review of the effectiveness of corrective and preventive actions was performed by the manufacturer. Internal audit and management review processes were effectively implemented to ensure adequate maintenance and a continual improvement of the quality management system. The internal audit program ensured that findings during internal audits were followed up in a timely manner.

The Quality management system documentation describes all processes, and the interactions are identified and described.

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

The auditee has furnished proof of maintaining a quality management system that fulfils the requirements mentioned under Section 2, Basis of the audit.
The audit objectives as defined in detail in the audit plan for this audit have been fulfilled.

The audited client is effectively controlling the use of the certification documents and marks.

■ No nonconformities were established what would affect the overall effectiveness of the QM-system.

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

Following pages of this report provide detailed information about the audit process.

Raymond Liu Digitally signed by Raymond Liu

Signature Audit Team Leader

Revision history

Rev no.	Date of report	Name of author	Description of change
0	2024-07-28	LA: Mr. Raymond Liu A/E: Mr. Gary Li A: Ms. Chita Qin	Initial revision

2. Executive summary

Holder of certificate/ approval (Auditee)	Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road, Economic Development Zone, Yangzhou, 225009 Jiangsu, P.R. China
Additional registered trade name or registered trademark of the manufacturer	N/A
Auditee's Representative	Mr. Tan Wei
Company's E-Mail	tanwei@chinamedline.com
Language of the audit	Chinese

Location(s) under the scope of the quality management system

#	Name and address	Activity	Senior Management (Name, Title)	No. of employees (FTE)	S	A
1	Yangzhou Medline Industry Co., Ltd. No. 108, Jinshan Road, Economic Development Zone, Yangzhou, 225009 Jiangsu, P.R. China	Design and Development, Manufacture and Distribution of Nerve Block Needles (Anesthetic Needles), Disposable Non-absorbable Sutures with Needles, Disposable Insulin Syringes, Disposable Syringes, Three-way Stopcocks, Auto-disable Syringes, Disposable Infusion Sets, Hypodermic Needles, IV Catheters, Surgical Blades, Feeding Tubes, Stomach Tubes, Suction Catheters, Disposable Safety Auto-disable Syringes, Disposable Safety Hypodermic Needles, Scalp Vein Sets, Disposable Vacuum Blood Collection Needles, Disposable Safety Vacuum Blood Collection Needles, Disposable Safety Scalp Vein Sets, Disposable Urine Bags, Surgical Brushes, Retractable Safety Syringes (No Gap Type), Safety Vacuum Blood Collection Needles (Pen Type), Disposable Syringes with Safety Needles, Disposable Safety Insulin Syringes, Filter Needles for single use, Safety Lancets, Disposable Surgical Procedure Kits (Masks, Medical Gauze, applicator, Medical tape, Disposable syringe, Infusion sets), Pre-filled Flush Syringes, Disposable Feeding Syringe.	Mr. Tan Wei, QMR	2	2	A
2	Yangzhou Medline Industry Co., Ltd. No. 1, Huafa Road, Development Zone, Yangzhou, 225000 Jiangsu, P.R. China	Design and Development, Manufacture, Distribution and ETO sterilization for products in scope	Mr. Tan Wei, QMR	80	2	A
3	Yangzhou Medline Industry Co., Ltd. No. 99, South Yangzi Road, Yangzhou, 225000 Jiangsu, P.R. China	Manufacture of Disposable Safety Hypodermic Needles.	Mr. Tan Wei, QMR	108	2	A

(FTE – full-time equivalent / S – Shift(s) / A – Audited in the scope this audit)

Description of the manufacturer

The organization include Office dept., PMC dept., Production dept., Quality dept., Sales Dept. There are three sites in QMS Scope.
Site 1 only is used as a licensed address only.
Site 2 includes all activities.
Site 3 includes quality inspection, storage and production.

	#	Audit criteria	A
☐	1	ISO 9001:2015	
☑	2	(EN) ISO 13485:2016	A
☐	3	Medical Device Directive 93/42/EEC	
☐	4	In Vitro Diagnostic Medical Device Directive 98/79/EC	
☐	5	Regulation (EU) 2017/745 (MDR)	
☐	6	Regulation (EU) 2017/746 (IVDR)	
☐	7	UK MDR 2002	
☐	8	ISO 15378:2017	
☐	9	TCP Taiwan ("Technical Cooperation Programme on exchange of Medical Device GMP and ISO 13485 Audit Reports between EU MDR/IVDR Notified Body Partners and R.O.C. TFDA Authorized Medical Device GMP Auditing Organizations")	
	10	Any additional requirement or standard	
	11	Defined processes and company's QMS documentation	A

(A – Applied by the Auditee)

Audit team leader, audit team members (incl. experts) and any accompanying persons

Name	Role*	Date From (YYYY/MM/DD)	To (YYYY/MM/DD)	Loc#	Criterion#
Mr. Raymond Liu	LA	2024-07-15	2024-07-17	2,3	2.11
Mr. Gary Li	A/E	2024-07-15	2024-07-17	2,3	2.11
Ms. Chita Qin	A	2024-07-15	2024-07-17	1,2,3	2.11

*(LA – Lead Auditor / A – Auditor / E – Expert / T – Translator / O – Observer / X – Others (to be described))

▪ (EN) ISO 13485 specific information

Scheme and Certification body:	EN ISO 13485 (TÜV Rheinland LGA Products GmbH - DAkkS accredited)

Combined/Integrated audit	NA		
Audit type	Re-certification audit	Location #(s) visited	1,2,3
Certificate number	SX 2110300-1 (to be issued)		
Certificate scope			
Recommendation of the auditor	Within the scope of the audit, the company has furnished proof that it maintains a quality management system in accordance with the above-mentioned standard. It can be confirmed that that the audit objectives are achieved. The appropriateness of the *proposed* certificate scope can be confirmed. **It is recommended that the EN ISO 13485 (TÜV Rheinland LGA Products GmbH - DAkkS accredited) quality system certificate should be issued.**		

NOTE: TÜV Rheinland LGA Products GmbH requests to be notified in case of any significant changes to the company's quality management system (e.g. changes to procedures which concern the design and development, manufacture and final inspection) during the time of validity of the certificate. In case significant changes are not notified, the certificate becomes invalid.

3. Scope

3.1. Objective

Assessment of the conformity of the auditee's quality management system, with the requirements referenced in the executive summary and assessment of the capability of the QMS to ensure compliance with applicable regulatory requirements (as indicated in audit criteria section).

MDL-QM-2024, Revision D/3 of the Quality Assurance manual is currently used by the auditee and was assessed during the audit with a positive result.

In addition, all reports established in the current certification cycle (reports linked to certificate with registration no. <SX 2110300-1>) were assessed prior to this audit. Follow-up activities as defined for this audit were performed.

Exclusion: None

■ Non-applicability

7.5.3 Installation activities
7.5.4 Servicing activities
7.5.9.2 Particular requirements for implantable medical devices

3.2. Corporate identity

■ No additional corporate name is used by the auditee.

3.3. Follow up on past nonconformities

■ Not applicable.

3.4. Significant changes since the previous audit

Have significant changes occurred since the previous audit and were subject in this audit? *	☒ No ☐ Yes, as follows:
Products / product groups	None
Facilities	None
Changes in the QA system / structure of the company / key personnel	None

* not for significant changes handled in separate projects

3.5. Outsourced processes

Subcontractor[1]	Supplied product (or service), outsourced activity	Confirmation of maintained QM system by	
		QM Certificate *	TR Audit **
Zhangjiagang Municipal CNNC Huakang Radiation Co., Ltd. Chuangye Road, Fenghuang Town, 215614 Zhejiang, P.R.China	Sterilization service for Radiation–gamma	Certified by TÜV SÜD, Cert. No.: Q8 063864 0006 Rev. 02, expiry date 2025-09-30	NA
Jiangsu Webest Medical product Co., Ltd. No. 5 Yingchun Road, industrial Park, 211700 Xuyi, JiangSu P.R. China	OEM of the product IV Catheters	No. Q6 056464 0019 Rev. 04 issued by TUV SUD, valid until 2026-05031	NA
Changzhou weite Medical Equipment Co., Ltd. Wugang Village, Zhenglu Town, Changzhou, 213115 Jiangsu China	OEM of the products Feeding tubes, Stomach tubes, Suction Catheters	Cert. # SX2068188 issued by TRLP, expiry date 2024-10-05	2023-07-20~21
Jiangsu Kangbao Medical Equipment Co., Ltd 78#, North Suzhong Road, Baoying, 225800 Yangzhou, PEOPLE'S REPUBLIC OF CHINA	OEM of the products Hypodermic Needles, Disposable Infusion Sets	No. Q6 050970 0016 Rev. 02, issued by TÜV SÜD, valid until 2026-01-31	NA

* QM Certificate – e.g. EN ISO 13485 certificate /
** TR Audit – Date of last TUV Rheinland audit

Additional control mechanisms for the above-mentioned companies were audited on a sampling basis.

3.6. Areas-shifts not audited / Obstacles / Refusals / Reliability

■ Processes of the auditee were audited according to the established audit plan.

[1] under MDD/IVDD consider definitions in ZLG 3.9 B17 and ZLG 3.9 B16

4. Audit process and findings

Within the scope of the audit, processes in the various departments of auditee have been audited in order to verify conformity with the requirements of the above-mentioned Directive/Regulation, standards and descriptions in the quality management system documentation. This verification was performed on a sampling basis, by interviews, assessment of the corresponding documentation and observation of processes.

The following QM system requirements were covered during the audit:

4.1. Management

4.1.1 QMS Documentation and Records

(ISO 13485:2016: 4.1, 4.2; ISO 9001:2015 / ISO 15378:2017: 4.1, 4.2, 4.3, 4.4, 7.5, 8.4, 9.1.1)
(EU MDR article 10(9),(16), annex IX chapter I 1, 2.2, 2.4, annex XI part A 4, 6.2, 6.4)

Audited area / organizational unit:	QMR	**Location(s) audited:**	1,2
Method of audit evidence collection:	Reported by CQ Site 1,2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities		
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	**QMS planning, Documents and records control** The company has documented a quality manual [QUALITY MANUAL # MDL-QM-2024, Rev. D/3] in accordance with EN ISO 13485:2016 that defines the scope of the QMS and identifies the non-applicable clauses. The quality manual contains references to QMS procedures and outlines the structure of the QMS documentation. The sequence and interaction of QMS processes is described [Quality Manual and Documentation control procedure]. The activities and the process audited are deemed to be in conformity with the audit criteria. A risk based approach is applied for the control of the Organization's processes; this was verified in the [Quality manual # MDL-QM-2024, Rev. D/3]. The organization has defined, documented, and implemented procedures to control documents [DOCUMENT CONTROL PROCEDURE # MDL-QP-4.2.4, Rev. D/1] and records [RECORD CONTROL PROCEDURE # MDL-QP-4.2.5, Rev. D/1] of both internal and external origin. [DOCUMENT CONTROL PROCEDURE # MDL-QP-4.2.4, Rev. D/1] ensures that obsolete copies of documents are retained per EN ISO 13485:2016 and applicable regulatory requirements. Document change control records [# MDL-QR-4.2.4-03, NO. 2024070801] show that the organization adequately controls changes to quality management system documents. During the audit, the organization provided documents and records promptly. The records reviewed were legible and readily identifiable. The activities and the process audited are deemed to be in conformity with the audit criteria. Changes to the quality management system are managed in accordance with the [Change control procedure # MDL-QP-4.1.4, Rev. D/1] to maintain conformity of the quality management system and devices produced.(ISO 13485, cl 4.2) **Documents and records reviewed:** Quality Manual: # MDL-QM-2024, Rev. D/3, dated on 2024-07-08. Master list of approved and effective documents : # MDL-QP-2021, Rev. D/1. Software platform for controlling QMS docs: None Validation record for software used in QMS: NA		

	Control of back-up of electronic records (Procedure, evidence): no electronic records. Sample of change management: Change control procedure # MDL-QP-4.1.4, Rev. D/1 Medical Device file: # MDL-CETF-BI-2022, Rev. A/0, for Disposable syring with needle
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.1.2 Outsourced processes

(ISO 13485:2016: 4.1.5; ISO 9001:2015 / ISO 15378:2017: 8.4)
(MDR art. 10(9))

Audited area / organizational unit:	Quality dept. **Location(s) audited:** 2
Method of audit evidence collection:	Reported by CQ Site 1 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	The extent to which the organization outsources manufacturing and service activities that affect the medical devices' ability to conform to specified requirements was established during the audit. In particular, the following processes are outsourced: • Sterilization service for Radiation–gamma • OEM of the product IV Catheters • OEM of the products Feeding tubes, Stomach tubes, Suction Catheters • OEM of the products Hypodermic Needles, Disposable Infusion Sets The manufacturer controls those processes through the following means: Relevant records have been checked about the implementation of such controls. A list of outsourced processes (including references to the organizations controls) is documented in section 3.5 of the audit report. Outsourced suppliers are qualified according to [purchasing control procedure # MDL-QP-7.4, Rev. D/1]. The activities and the process audited are deemed to be in conformity with the audit criteria. As consequence of this assessment, it is deemed that proper controls are implemented and no additional audit is required by the NB.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.1.3 Management responsibility

(ISO 13485:2016: 5.1, 5.2, 5.3, 5.4, 5.6, 8.4; ISO 9001:2015 / ISO 15378:2017: 4.1, 4.2, 5.1, 5.2, 5.3, 6.1, 6.2, 6.3, 7.4, 9.1.3, 9.3) (EU MDR article 10(9), annex IX chapter I 2.2, annex XI part A 6.2)

Audited area / organizational unit:	QMR **Location(s) audited:** 2
Method of audit evidence collection:	Reported by CQ Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	It was verified that a quality policy and objectives have been set at relevant functions and levels within the organization. It was ensured the quality objectives are measurable and consistent with the quality policy and are reviewed for achievements on periodical basis [once a year]. It was confirmed that appropriate measures are taken to achieve the quality objectives. The Organizational structure is defined in the Organizational chart [in chapter 0.2.2 of QM]. Top management has documented the appointment of a management representative. It was verified that responsibilities and authorities (e.g., management representative) were established within the Organization [Top Management of the audited Organization is Mr. Qi Jiangzhong]. The Company conducts Management Reviews per a documented procedure [Management review control procedure # MDL-QP-5.6, Rev. D/1] and at planned intervals [once a year]. It is evident from the Management Review records reviewed (Report dated related to the management review occurred on: 2024-07-12), covering the period: [July Y2023 to June Y2024] that the Management Reviews cover opportunities for improvement, the need for changes to the quality management system (including quality policy & quality objectives), the required inputs per clause 5.6.2 and outputs per clause 5.6.3 of EN ISO 13485:2016 / ISO 13485:16. Overall the Management Review contains sufficient detail to support Top Management's decision that the Quality Management System is suitable, adequate, and effective. The activities and the process audited are deemed to be in conformity with the audit criteria. Based on the assessment results of the Management, Measurement, Analysis & improvement, Design and development, Production and Purchasing processes within the Organization, it was confirmed that management provides the necessary commitment to those processes. **Documents and records reviewed:** Latest management review have been done on 22024-07-12: • Management review plan # GMDL-QR-5.6-01, was established and approved by GM. • Management review input # MDL-QR-6.2-06.The review included quality objectives review, CAPA, customer complaint, product non-conformance, quality planning & accomplishment, suitability and effectiveness of quality system and statistic from internal audit/product compliant, etc. • Management review report # MDL-QR-5.6-03 was checked. Review output including: • The QMS is suitable, adequate and effective. • No need to change the quality policy and quality objective.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.

Nonconformities:	Major:	0	Minor:	0
Observations:	None			
Follow-up items for the next audit	None			

4.1.4 Human resources

(ISO 13485:2016: 5.5, 6.1, 6.2; ISO 9001:2015 / ISO 15378:2017: 7.1, 7.2, 7.3)
(EU MDR article 15)

Audited area / organizational unit:	HR dept.	**Location(s) audited:**	2

Method of audit evidence collection:

Reported by CQ
Site 2 audited on-site
Method of audit evidence collection:
☒ interview with auditee
☒ review of documents and records
☐ observation of process and activities

Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):

The organization has determined the necessary competencies for personnel performing work affecting product quality, provided appropriate training, and made personnel aware of the relevance and importance of their activities on product quality and achievement of the quality objectives. Ensured records of training and competencies are maintained.

Documents and records reviewed:

Job qualification

JD # MDL-QS-6.2-01, rev. D/1 for the organization was reviewed. No change from last audit. The following information was reviewed:

- Qualification of personal are spot checking: new employee Ms. Zhang Ailan, joined on 2023-03-22, QC, training record including: new employee orientation training # MDL-QR-6.2-03 (items including company overview, basic knowledge learning, etc., after a three-months training, Ms. Zhang transfer application was approved on 2024-05-20, and was appointed as a QC by QMR).
- EO sterilization operator: the training record # MDL-QR-6.2-03, dated on 2024-04-12, for EO sterilization operator Mr. Qin Yun, Mr. HAN, Mr. Zhang , who are operator from 2 sites, were checked, the training items including operating procedures and precautions. Through oral and writing assessment, all personnel passed the assessment.

Training

The H&R department shall formulate the company's annual training plan every year. Then, the training performed according to the annual training plan. The effectiveness of training evaluated through written assessment, practical assessment, etc. No significant change from last audit.

Training plan Y2024 # MDL-QR-6.2-01, was approved by GM on 2023-12-26, items including, QMS training, procedures and WIs, products know ledge training, etc. 2 training was sampled and checked, including:

- Microbiology training record # MDL-QR-6.2-03. Trainer: Mr. Tan Wei. Trainee: quality dept. staff, e.g. Ms. Yao Huizhu (QC). Training was conducted on 2024-02-21. The training effectiveness was verified by writingl test, and all staffs got positive results.
- Production operating procedures training records # MDL-QR-6.2-03: Trainer: Mr. Wang Delin. Trainee: production dept. staffs, e.g. Mr. Yang Bin (production staff). Training was conducted on 2024-05-16. The training effectiveness was verified by writing test, and all staffs got positive results, e.g.: Mr. Yang Bin, the score was 94, met requirements.

Follow-up items from previous audits/ assessments:

None

Follow-up of SCN:	None			
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.			
Nonconformities:	Major:	0	Minor:	0
Observations:	None			
Follow-up items for the next audit	None			

4.2. Measurement, analysis and improvement

4.2.1 Data analysis, statistical methods and quality data reporting

(ISO 13485:2016:8.1, 8.2.5, 8.4; ISO 9001:2015 / ISO 15378:2017: 9.1)
(EU MDR article 10(9 m))

Audited area / organizational unit:	Quality dept.	**Location(s) audited:**	2
Method of audit evidence collection:	Reported by CQ Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities		
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	The Company has established procedures for measurement, analysis and improvement which address the requirements of EN ISO13485:2016 and applicable regulatory requirements. This includes procedures for monitoring and measuring product conformity throughout product realization (Product monitoring and measurement control procedures # MDL-QP-8.2.6, Rev. D/1), as well as procedures that provide for mechanisms for feedback to provide early warnings of quality problems (Feedback control procedure # MDL-QP-8.2.1, Rev. D/1), in the implementation of corrective action and preventive action (CAPA control procedure # MDL-QP-8.5, Rev. D/1.) and the Quality Management System processes. The activities and the process audited are deemed to be in conformity with the audit criteria. It was determined that appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including: • Management review - QC data 2023 It was confirmed that data from these sources are accurate and analyzed according to a documented procedure (Data analysis control procedure # MDL-QP-8.4, Rev. D/1 for the use of valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action. It was determined that relevant information regarding nonconforming product, quality management system nonconformities, corrections, corrective actions, and preventive actions has been supplied to management for management review. This was confirmed in the MR. **Documents and records reviewed:** Feedback control procedure # MDL-QP-8.2.1, Rev. D/1. The sources include feedback from enduser, trend analysis of complaints, incidents, production data, QC data, feedback from employees, etc. QC and production data was viewed: QC data from July Y2023 to June Y2024 was viewed, which was presented for the management review - including percentage of rejects per departments, there were no CAPAs required based on the results. Objectives from July Y2023 to June Y2024 results were defined and Quality objective checklist was reviewed, e.g.: for production dept., the		

	product one-time pass rate was 100%, which was more than 99.5% of the target requirements; etc. As defined in management review: Data analysis data sourced from audit, the determination, collection and analysis of data. If the analysis of data shows that the quality management system is not suitable, adequate or effective, these data statistics will be used as input to the improved procedures (such as Corrective action and/or Preventive action) e.g. data analysis from July Y2023 to June Y2024 has been established and was checked. Quality objective for Y2024 remained the same.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.2.2 Nonconformities investigation. Corrective and Preventive Actions

(ISO 13485:2016: 8.5; ISO 9001:2015 / ISO 15378:2017: 10.1, 10.2, 10.3)
(EU MDR article 10(9 I))

Audited area / organizational unit:	Quality dept. **Location(s) audited:** 2
Method of audit evidence collection:	Reported by CQ Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	**CAPA PROCESS** Investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible. It was confirmed investigations are commensurate with the risk of the nonconformity. It was confirmed that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices. It was ensured corrective actions and preventive actions are appropriate to the risk of the non-conformities or potential nonconformities encountered. CAPA DB: internal audit. Number of CAPAs opened since last audit: 0 Number of CAPAs closed since last audit: 4 **Rationale for Sampling:** Communicated with client and confirmed that, 4 CAPA from internal audit since last audit. So, one of them was sampled. For CAPA resulting from internal audit, refer to section " Internal audits" **IDENTIFICATION AND CONTROL OF NONCONFORMING PRODUCT** The Company has established controls in [Nonconforming product control procedure # MDL-QP-8.3, Rev. D/1] to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. It is evident from the product NCRs [records # MDL-QR-8.3-01] sampled that these procedures are implemented and effective, and that appropriate dispositions are made, justified, and documented. When approving NC product under concession,

	documentation of the justification for use of and the signature of the individual(s) authorizing the use is completed, and that risk-based decision making was used and determined that the device meets required specifications. Communication to external parties is communicated when it is determined that they are the source of the NC product. The Company has established requirements for the actions that must be taken when nonconforming product is detected after it has been delivered in [Advisory notification control procedures # MDL-QP-8.2.3-01, Rev. D/1; Adverse event control procedures # MDL-QP-8.2.3-03, Rev. D/1; Recall control procedure # MDL-QP-8.2.3-02, Rev. D/1]. From the records reviewed [WHAT RECORDS] it is evident that this process is implemented and effective. The actions that are taken are commensurate with the risk of the nonconformity. NC database: IPQC Number of NCs opened since last audit: 0 Number of NCs closed since last audit: 2 **Rationale for Sampling:** Communication with the organization, the nonconformity only came from IPQC on site 2. No NC on site 3. The process was similar, so one of them was sampled. NC Record # MDL-QR-8.3-01, NO. 20240428011 Opened: 2024-04-28 Status: closed Issue: The tip of the needle (no.240420-2271, quantity: 4500pcs) punctured the sheath. Risk: Product damage Correction/Decision: Select and use Corrective Action: Train employees.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.2.3 Internal audits

(ISO 13485:2016: 8.2.4; ISO 9001:2015 / ISO 15378:2017: 9.2)
(EU MDR: no specific requirements)

Audited area / organizational unit:	Quality dept. **Location(s) audited:** 2
Method of audit evidence collection:	Reported by CQ Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	[Internal audit control procedure # MDL-QP-8.2.4, Rev. D/1] describes the responsibilities and requirements for planning, conducting, and recording QMS audits. The [INTERNAL AUDIT SCHEDULE # MDL-QR-8.2.4-02, NO. 202407-1] was reviewed. Audits are required to be conducted [once a year] The following audit reports were reviewed:

	It was verified that the internal audit [PLAN # MDL-QR-8.2.4-02, NO. 202407-1, dated on 2024-06-10/REPORT # MDL-QP-8.2.4-05, dated on 2024-07-09] includes the criteria and scope of the audit. Processes are audited to [ISO 13485:2016] requirements. [PLAN/REPORT] includes a description of previous audit results. [AUDIT REPORT for the Year 2024] resulted in [4] findings. It was verified that appropriate follow-up activities were taken and corrections and corrective actions were taken without undue delay. Auditors are required to be qualified by [external certification] per [Internal audit control procedure # MDL-QP-8.2.4, Rev. D/1]. Qualification records were reviewed for the following auditors: 4 It was confirmed that the internal audits include provisions for auditor independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions. **The following CAPAs resulting from the internal audit above were checked:** • CAPA # MDL-QR-8.5-02, NO. 20240703 **Documents and records reviewed:** The general internal audit is at least once a year, and additional audit would be arranged by management representative if necessary. Last internal audit performed on 2024-07-08~09. The organization have been established the audit plan and audit report by each audit team. The relevant documents were taken for sample, including: • Internal audit plan # MDL-QR-8.2.4-02, NO. 202407-01, dated on 2024-06-10, approved by GM. • Internal audit checklist # MDL-QR-8.2.4-03, was established according to the regulatory. • Internal audit report # # MDL-QR-8.2.4-05, dated on 2024-07-09. • CAPA report # MDL-QR-8.5-02, NO. 20240703: Issue: the material identification card from IPQC for material: needle cap, on site was damaged, Root Cause: the material identification card was damaged when the employee filled in the card, but the new identification card was not replaced in time. Corrective Action: Conduct training for employees. Effectiveness Check: has been closed by QMR on 2024-07-13.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.2.4 Feedback, Complain handling, PMS, PMCF, PMPF

(ISO 13485:2016: 8.2.1, 8.2.2; ISO 9001:2015 / ISO 15378:2017: 8.5.5, 9.1.2)
(EU MDR article 10(8),(9),(10), 83, 84, 85, 86)

Audited area / organizational unit:	Sales dept.	**Location(s) audited:**	2
Method of audit evidence collection:	Reported by CQ Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records		

Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	☐ observation of process and activities The Company has made effective arrangements through [Feedback control procedure # MDL-QP-8.2.1, Rev. D/1 and Complain control procedure # MDL-QP-8.2.2, Rev. D/1] for gaining experience from the post-production phase, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process. It is evident from the complaint records reviewed that this process is implemented and effective. Furthermore, the records show that information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate. **ADVERSE EVENT REPORTING AND ADVISORY NOTICES** The Company has defined and documented procedure [Adverse event control procedures # MDL-QP-8.2.3-03, Rev. D/1.] for the evaluation of quality problems involving distributed product for potential issuance and implementation of adverse events reporting and advisory notices based on the applicable regulatory requirements. When it is decided to not report complaints according to an established procedure, the rationale for this decision is documented in the complaint record. **Complaint Handling Software / Database:** Communication with QMR, no complaint since last audit. The customer feedback control procedure # MDL-QP-8.2.1, rev. D/1. No change from last audit. Feedback record for production # MDL-QR-8.3-03: data has been gathered from production, e.g.: conforming rate from quality dept. The organization performed the satisfaction survey every year through the telephone, e-mail, online questionnaire, and the field questionnaire. The customer satisfaction survey from post-production of Y2023: 12 feedback sheets was sent to client and 9 back with identified as “effective” feedback by sales dept, and the average survey score was 87.4. The data are analysis by QA dept., and output to management review, risk management process (data sent to technical dept. for further analysis). One customer satisfaction survey form # MDL-QR-8.2.2-02 D/0 has been sampled to check and acceptable, details were as following: • From Mingbo Ketai Medical Device Co., Ltd, competed by Mr. Ren Shunlu on 2023-09-28, the satisfaction was focused on the: communication, quality, sample, delivery date, and service, price, e.g., for quality, score 19, for delivery date, score 9, for service, score 19, the final survey score was 93, belonged to “very satisfied”. **Complaint** The customer complaint handling control procedure # MDL-QP-8.2.2, rev. D/1. No change from last audit. Since last audit, there was no complaint and had been concluded. The audit team reviewed the blank customer complaint handling record # MDL-QR-8.2.2-01 D/0, including the complaint description, handling suggestion, and conclusion. Communicated with QMR, no vigilance case occurred till this audit. And no adverse event, recall or advisory notice happened till this audit.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None

Follow-up items for the next audit	None

4.3. Design and Development

(ISO 13485:2016: 7.3; ISO 9001:2015 / ISO 15378:2017: 8.3)
(EU MDR article 10(9), 61, annex I, annex IX chapter I 2.2, annex XIV)

Audited area / organizational unit:	Technical dept. **Location(s) audited:** 2
Selected design file and rationales for the selection	**Selected device subcategory / device code based on the audit programs: Auto-disable Syringes** **Selected design file: DHFs# MDL-QR-7.3-02** Rationales for the selection: ☐ complaints or known problems with a particular device ☒ product risk ☒ recent design changes, particularly design changes made to correct quality problems associated with the device design ☐ age of design (prefer most recent) ☐ designs that have not been recently audited ☐ other: Reported by GL
Method of audit evidence collection:	Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	**IDENTIFY DEVICES WHICH REQUIRE D&D** The Company has identified their devices that are, by regulation, subject to design and development procedures. Design process is conducted in accordance with the procedure Design & Development control procedure # MDL-QP-7.3. Yangzhou Medline Industry Co., Ltd. is the legal manufacturer of medical devices that are sold in China, Europe market and South America etc. For products where design controls are a permitted exclusion, it was verified that the organization has available and is maintaining adequate technical documentation to demonstrate conformity to safety and performance requirements and other relevant regulatory requirements This was verified in: DHFs# MDL-QR-7.3-02 **Selected Design File and Rationale for the selection** The following Design and Development Project of Auto-disable Syringes (DHFs: MDL-QR-7.3-02) was selected based on the product risk and recent design changes. Records related to the design project selected above are included in the following design and development file: DHFs:MDL-QR-7.3-02 Exemplary records extracted from this DHF and corresponding to the different phases of the implemented design and development process, were reviewed during this audit (see following information for the details). **D&D PLANNING** It was verified that the design and development process is planned and controlled. The review the design plan for the selected design and development project provided evidence of implementation of the established the design and development activities; including the design and development stages, the review, verification, validation, and

design transfer activities that are appropriate at each stage; and the assignment of responsibilities, authorities, and interfaces between different groups involved in design and development.

records reviewed:

Design and development plan and task record (DHFs# MDL-QR-7.3-02 -02/-03)

D&D QMS

It was verified that the established design and development procedures have been applied to the Auto-disable Syringes (DHFs: MDL-QR-7.3-02) project and conforms to the design and development stages. It was verified that the procedures establish mechanisms for addressing any incomplete, ambiguous, or conflicting requirements.

The procedures listed below were reviewed in the relevant design and development tasks of this report:

- Design & Development control procedure # MDL-QP-7.3.

D&D INPUTS

It was verified that design and development inputs for the Auto-disable Syringes were established, reviewed and approved; addressing customer functional, performance and safety requirements, intended use, applicable regulatory requirements, and other requirements including those arising from human factors issues, essential for design and development.

Any risks and risk mitigation measures identified during the risk management process are used as an input in the design and development process.

It was confirmed that the design and development inputs are complete, unambiguous, and not in conflict with each other.

records reviewed:

D&D Input record #MDL-QR-7.3-04 -01

D&D OUTPUTS, TRACEABILITY

It was verified that the design and development outputs essential for the proper functioning of the medical device have been identified. Outputs include device specifications, specifications for the manufacturing process, the quality assurance testing, device labeling and packaging, and other relevant requirements.

records reviewed

D&D output record #MDL-QR-7.3-06-01

D&D RM, RM in V&V

It was verified that risk management activities are defined and implemented for product and process design and development. It was confirmed that risk acceptability criteria are established and met throughout the design and development process.

Any residual risk is evaluated and, where appropriate, communicated to the customer (e.g., labeling, service documents, advisory notices, etc.).

Possible hazards are identified in both, normal and fault conditions, including those arising from human factors issues. It was confirmed that any unacceptable risk is reduced to acceptable level.

Design Verification activities (and validation) are conducted to reduce the identified risks to an acceptable level.

It was verified that for devices containing medicinal substances, requirements for storage, sampling and identification testing of starting materials, in accordance with defined technology requirements of Y2017021716-18.

records reviewed:

- Risk management report #MDL-FXFX2024-FII-13 Annex 1
- Verification record #Y2017021718

D&D VALIDATION

It was verified that design and development validation data show that the approved design meets the requirements for the specified application and intended use. Design

validation testing is adjusted according to the nature and risk of the product and element being validated.
It was verified that clinical evaluations and / or evaluation of the medical device safety and performance were performed as part of design validation if required by national or regional regulations.

Clinical Evaluation Procedure DOC #MDL-QP-9.5 rev D1 establishes requirements for conducting and reporting clinical evaluation to demonstrate safety and performance of a medical device throughout its life cycle, including the pre- and post-market phases. Key points include: Puncture hurt caused by needle, infection.
records reviewed:
Clinical evaluation report #MDL-CETF-FII-14.

D&D REVIEWS
It was verified that design reviews were conducted at stages as required by the design and development plan. It was verified that the reviewed contained results of design and development to meet requirements. It was confirmed that action items were identified and proposed.
Participants to design review stages included at least one individual who does not have direct responsibility for the design stage being reviewed.
records reviewed:
D&D input review record (DHFs# MDL-QR-7.3-02-05)
D&D output review record (DHFs# MDL-QR-7.3-02-07)

DESIGN TRANSFER
It was verified that product and production specifications are fully documented prior to design release for transfer to production.
Device Master Record: # MDL-CETF-BI-2022, Rev. A/0
records reviewed:
Trial production record (DHFs# MDL-QR-7.3-02-10)

D&D CHANGES and RETROSPECTIVE ANALYSIS
It was verified that control of design and development changes, including changes to manufacturing processes affecting the characteristics of the medical devices, are subject to design and development verification and validation, as applicable, addressing the new or impacted risks.
It was confirmed that design changes have been reviewed for the effect on products previously made and delivered, and that records of review results are maintained.
It was verified that product and production specifications are fully documented prior to release design changes for transfer to production.

Sampling rationale:
The recent change occurred on 2023-05-08. The change control was checked.

Documents and records reviewed:
D&D change record #MDL-QR-424-03
-Change description: There was convex rings at the needle guidepost and the inner wall of the sheath (Original). There were convex ring and concave ring at the needle guidepost and the inner wall of the sheath (After change).
-The product after change was verified. Risk management was updated, and the risk was accepted.

Follow-up items from previous audits/ assessments:	None			
Follow-up of SCN:	None			
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.			
Nonconformities:	Major:	0	Minor:	0
Observations:	None			
Follow-up items for the next audit	None			

4.4. Production and Service Controls

4.4.1 Planning of product realization, Production and Service provision. Monitoring and measurement of products

(ISO 13485:2016: 7.1, 7.5.1, 7.5.2, 7.5.5, 7.5.8, 7.5.9, 7.5.10, 8.2.6; ISO 9001:2015 / ISO 15378:2017: 6.1, 7.1, 8.1, 8.5.1, 8.5.2, 8.5.3, 8.5.4,8.6)
(EU MDR article 10(7),(9), annex I chapter I, annex IX chapter I 2.2 c,d, annex XI part A 6.2)

Audited area / organizational unit:	Quality dept. Production dept. Technical dept.
Location(s) audited:	2,3
Selected production process and rationales for the selection	**Selected production technologies / horizontal codes that describe technologies or processes:** MDT 2001, MDT 2002, MDT 2008 **Selected sterilization methods: Gas – ethylene oxide in-house sterilization** **Selected production processes:** injection molding process, Primary packaging process Rationales for the selection: ☐ corrective and preventive action indicators of process problems or potential problems ☐ use of the production process for higher risk products ☒ use of production processes that directly impact the ability of the device to meet its essential design outputs ☐ new production processes or new technologies ☒ use of the process in manufacturing multiple products ☐ processes that operate over multiple shifts ☐ processes not covered during previous audits ☐ other:
Method of audit evidence collection:	Reported by RL Site 2,3 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	Planning of product realization is implemented by: • Defining specification for the finished product • Quality plans • DMR • Defining criteria for product release • Implementing the risk reduction measures defined in the risk management / pFMEA This is defined in the procedure: Planning of product realization control procedure # MDL-QP-7.1-02, rev. D/1. The auditor selected for assessment of the product realization process, the production process [injection molding process and primary packaging process] applied for the [Disposable Syringes (site 2) and Disposable Safety Hypodermic Needles (site 3)] basing on the following rationale: 1. Use of production processes that directly impact the ability of the device to meet its Essential design outputs 2. Use of the process in manufacturing multiple products The assessment of the production process was performed by: • On-site visit to the production area • Evaluation of the outsourced manufacturing process basing on records • Audit at critical supplier's premises • Verification of DMR and DHF for the selected process

Description
Disposable Syringes (site 2)

- The manufacturing of the Disposable Syringes including: the molding injection, assembling process, primary package, EO sterilization.

MDT 2002: was considered during audit, such as injection molding process.
MDT 2008: clean room control refer to section 6.4.

- Description of the production process selected for review (list the main production steps)
- Production flow-chart # MDL-CETF-BI-10

Injection molding process and primary package process was checked on-site.
Injection molding process:
SOP # MDL-QR-7.3-14
Injection molding machine, equipment no.: ZS06
Process record # MDL-QR-7.5.1-02, s/n: 0023434, equipment no.: ZS06, mould no.: ZM143, production date 2024-07-17, for syringe sheath, process lot no.: 240705-ZS06, type: 10mL, the first article inspection result was available.
Production parameters were recorded in injection molding IPQC record # MDL-QR-8.2.6-39, met the SOP requirements.

Primary packaging process:
SOP # PC-HS-BP-01
Package machine, equipment no.: BZ09
Process record # MDL-QR-7.5.1-05, s/n: 0006313, equipment no.: BZ09, product name: Disposable Syringes, type: 5mL, 23Gx32mm, contract no.: PO#4110005587, product lot no.: 20240412, production date 2024-07-17, used materials information were recorded.

Disposable Safety Hypodermic Needles (site 3)

- The manufacturing of the Disposable Syringes including: the molding injection, assembling process, primary package, EO sterilization.

MDT 2002: was considered during audit, such as injection molding process.
MDT 2008: clean room control refer to section 6.4.

- Description of the production process selected for review

Production flow-chart # MDL-CETF-FII-10
Injection molding process, primary package process was checked on-site.
Injection molding process:
SOP # MDL-FZCZSZ-01-02
Injection molding machine, equipment no.: ZS73

Primary packaging process:
SOP # MDL-FZCZSZ-01-02
Injection molding machine, equipment no.: ZS73

No ongoing production activities during the visit to the workshops site 3.

It was verified that the process as selected above is planned, carried out, monitored and controlled to ensure that product conforms to specification. It was also confirmed that regulatory and statutory product requirements are met. Necessary controls, conditions, and risk management activities are established.

RISK MANAGEMENT
The organization has established a risk management policy [per risk management control procedure # MDL-QP-7.1-01, rev. D/1], in accordance with [ISO 14971:2019]. [Risk management control procedure # MDL-QP-7.1-01, rev. D/1] describes how the organization analyzes, evaluates, and controls product risk throughout product realization. Risk acceptability criteria are clearly defined. Records of risk management activities were reviewed:

Risks identified for the sampled production process are documented in the:
Risk management file:
[Risk management plan # MDL-FXFX2023-04-01 for Disposable Syringes.]
[Risk management report # MDL-FXFX2023-04, rev. A/1 for Disposable Syringes.]

Examples of risks assessed:
There was no change for product design. Risk management for production and postproduction at site2 was conducted. The following information was collected:

- Customer feedback
- Customer complaint
- Production chains, including raw material, production process nonconformity and product nonconformity.
- Literature retrieval
- Adverse events for the similar marketed device

The identified hazes have been controlled. After risk control, the residual risk and risk/benefit were acceptable.
In addition, the risks for extension production at site 3 was conducted. The identified risks include production environment, equipment, and storage etc. Risks were evaluated and control measures were taken, e.g.

- For production environment control, the environment requirement (ISO class 8) was identified. Environment control and contamination control were established. Environment was verified to conform to ISO class 8.
- For equipment control, the equipment requirements were identified. Precise of equipment was verified. Calibration was conducted at the new site.
- For storage control, the storage requirements were identified and verified.
- Etc.

After risk control, the residual risk and risk/benefit were acceptable.

DMR Review
It was determined that the Organization has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications. The extent of traceability has been established and is based on the risk posed by the device in the event the device does not meet specified requirements.
For the [Disposable Syringes], the DMR assessed during this audit is: [MDN-CETF-BI-2022, rev. A/0].

Documents and records reviewed:
DMR document # MDL-CETF-JI-2022 A/0 for safety hypodermic needle was checked.

- Quality objective was established.
- The intend use and specifications were defined
- The IFU, label and storage were established.
- The production flowchart, production instructions and inspection instructions were established.
- The work environment and equipment requirements were established.
- Etc.

DHR Review
For the selected product above, it was verified that the manufacturer establishes device history records (DHR) in accordance with EN ISO 13485:2016, applicable regulatory requirements, and the Device Master Record (DMR).
In particular the following elements were verified:

Site 2:

Product: Disposable Syringes
SN or Lot #: 20240523
Date of Manufacture: 2024-05-22
Quantity Manufactured: 100,800pcs
Traceability of raw materials /component verified for:

- **Assembling record # MDL-QR-7.5.1-04, s/n: 0008508, used components were recorded, e.g., rubber stopper, lot no.: J2240524-107, qty.: 72,000pcs; plunger, lot no.: 240611-2S17, qty.: 72,000pcs; etc.**

- **Printing production record # MDL-QR-7.5.1-03, s/n: 0002560, equipment no.: YX11, production date 2024-06-19, used raw material information recorded, e.g., ink lot no.: J231225-36; silicone oil lot no.: J240105-32, part: barrel, type: 1mL, the first article inspection result was available.**
- **Injection molding production record # MDL-QR-7.5.1-02, s/n: 0016994, equipment no.: ZS13, mould no.: ZM303, production date 2024-05-15, raw material PP, model: 1600E, lot no.: J240226-18, product type: 3mL, product part: barrel; the first article inspection result was available.**
- **Packaging production record # MDL-QR-7.5.1-05, s/n: 0006459, equipment no.: BZ12, type: 3mL, 24Gx25mm, contract no.: PO#4110005659, product lot no.: 20240523, production date 2024-06-22, used materials information were recorded, e.g. coated paper lot no.: J240611-31, qty.: 25kg; PE film, lot no.: J240613-10, qty.: 36kg; the first article and process inspection result was available.**

Results of Inspections and Tests: pass, refer to section 8.2.6.
Quantity Released for Distribution: 20,000pcs
Labeling:
Labeling Approval Date: 2024-06-22
Labeling Approver: QC
Final Release of Product: 2024-07-03
Person authorizing the release: QMR, Mr. TAN Wei
Evaluation and description of the product release process: refer to 8.2.6

Site 3:

Product: Disposable Safety Hypodermic Needles
SN or Lot #: 2024060401
Date of Manufacture: 2024-06-03
Quantity Manufactured: 100,000pcs
Traceability of raw materials /component verified for:

- **Assembling record # MDL-QR-7.5.1-16, s/n: 0000689, used components were recorded, e.g., needles, lot no.: J240305-1, qty.: 100,400pcs; needle holder, lot no.: 240603-2S73, qty.: 100,100pcs; etc.**
- **Injection molding production record # MDL-QR-7.5.1-02, s/n: 0020509, equipment no.: ZS72, mould no.: ZM198, production date 2024-06-03, raw material PP, model: 1600E, lot no.: J240528-1, product type: 30G, product part: anti needle puncture sheath; the first article inspection result was available.**
- **Packaging production record # MDL-QR-7.5.1-05, s/n: 0005630, equipment no.: BZ24, type: 30Gx1/2", contract no.: MDLYP20240510, product lot no.: 2024060401, production date 2024-06-04, used materials information were recorded, e.g. coated paper lot no.: J240521-30, qty.: 24kg; PE film, lot no.: J240514-14, qty.: 38kg; the first article and process inspection result was available.**

Results of Inspections and Tests: pass, refer to section 8.2.6.
Quantity Released for Distribution: 100,000pcs
Labeling:
Labeling Approval Date: 2024-06-04
Labeling Approver: QC
Final Release of Product: 2024-06-15
Person authorizing the release: QMR, Mr. TAN Wei
Evaluation and description of the product release process: refer to 8.2.6

The identification of the product throughout the production process is implemented in accordance with the procedure [traceability control procedure # MDL-QP-7.5.8, rev. D/1]. The status of the product during production and inspection process is identified by means of [production process record, inspection record, etc.]

PRODUCT INSPECTION

The organization monitors and measures the characteristics of the product to verify that product requirements have been met.
For the selected product above, it was verified by reviewing in-process (IPQC) and final acceptance activities (FQC) that acceptance are documented and meet specified

documented requirements. The extent of acceptance activities is commensurate with the risk posed by the device.

The following records were selected for review for the sampled product: **Disposable Syringes, lot no.: 20240523 (site 2) and**
Disposable Safety Hypodermic Needles, lot no.: 2024060401 (site 3).
Site 2:
IPQC
Name of IPQC: injection molding process
Applied test instruction: IPQC SOP # MDL-QS-8.2.6-07
Statistical technique applied for sampling: as per IPQC SOP # MDL-QS-8.2.6-07
Record seen: IPQC record # MDL-QR-8.2.6-39, equipment no.: ZS17, mould no.: ZM170, part: plunger, type: 3mL, the injection molding process parameters for temperature, time, pressure, etc. was recorded per 2h, the first article and process inspection result was available.
Measuring device used: visual inspection
Result: Pass

FQC
Name of FQC:
Applied test instruction: FQC SOP # MDL-QS-8.2.6-08
Statistical technique applied for sampling: as per FQC SOP # MDL-QS-8.2.6-08
Record seen: FQC record # MDL-QR-8.2.6-02, s/n: CJ20240523, the inspection items included pH value, EO residual, sterile, tolerance, appearance, dimension, piston, residual volume, etc.
Measuring device used: EO residual, Gas chromatograph, equipment no.: YQ43, etc.
Result: Pass

Site 3:
IPQC
Name of IPQC: primary packaging process
Applied test instruction: IPQC SOP # MDL-QS-8.2.6-11
Statistical technique applied for sampling: as per IPQC SOP # MDL-QS-8.2.6-11
Record seen: IPQC record # MDL-QR-8.2.6-43, equipment no.: BZ24, type: 30Gx1/2", the primary packaging process parameters for forming temperature and sealing temperature, pressure, etc. was recorded per 2h, the first article and process inspection result was available.
Measuring device used: packaging strength, tensile testing machine, equipment no.: YQ57
Result: Pass

FQC
Name of FQC:
Applied test instruction: FQC SOP # MDL-QS-8.2.6-12
Statistical technique applied for sampling: as per FQC SOP # MDL-QS-8.2.6-12
Record seen: FQC record # MDL-QR-8.2.6-02, s/n: CJ20240523, the inspection items included appearance, dimension, connection strength, sharpness, EO residual, sterility, etc.
Measuring device used: connection strength, tensile testing machine, equipment no.: YQ57; EO residual, Gas chromatograph, equipment no.: YQ43, etc.
Result: Pass

Product release take place in the following way:
Site 2:
Release form # MDL-QR-8.2.6-19, s/n: CJ20240523, on 2024-07-03, Disposable Syringes, lot no.: 20240523, model: 3mL 24Gx25mm, sterilization lot no.: 240625-3-241, approved by QMR Mr. TAN Wei, including materials check, product records check, inspection records check, sterilization record check, etc. met the SOP#MDL-QS-8.2.6-05.

Site 3

Release form # MDL-QR-8.2.6-19, s/n: CJ2024060401, on 2024-06-15, Disposable Safety Hypodermic Needles, lot no.: 2024060401, model: 30Gx1/2", sterilization lot no.: 240607-3-223, approved by QMR Mr. TAN Wei, including materials check, product records check, inspection records check, sterilization record check, etc. met the SOP#MDL-QS-8.2.6-05.

PRESERVATION OF PRODUCTS AND CUSTOMER PROPERTY

[Product preservation control procedure # MDL-QP-7.5.11, rev. D/1] is established for preserving the conformity of product and constituent parts of a product during internal processing, storage, and transport.
It was verified that risk control and mitigation measures are also applied to transport, installation and servicing, in accordance with the medical device organization's risk management practices.

[Customer property control procedure # MDL-QP-7.5.10, rev. D/1] defines the controls established to identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. It was verified the organization treats patient information and confidential health information as customer property.

records reviewed:

No customer property has happened till this audit, but the blank template of customer property registration form was checked, the customer name, property name, ID, quantity, receipt date, current status, etc. were identifiable.

Site 2:
In raw material and final product warehouse, raw material and final products were bagged and placed on pallet with label attached. There were no special environment requirements. The storage environment was clean. Insect-proof and rat-proof measures were taken, e.g. UV light an lifted threshold.

Site 3:
There were no product during audit. The storage environment, including insect-proof and rate-proof measures, were verified according to # MDL-QP-7.5.11 Rev. D/0. The semi-product storage at site 3 was in cleanroom.

Risk management file / pFMEA:

Examples of risks assessed:

The following aspects for each main hazard have been sufficiently addressed:
The risk analysis, the risk evaluation.
Risk acceptability criteria, including risk reduction endpoints.
Risk control measures are applied in the following order of priority:
Eliminate or reduce risks as far as possible through safe design and manufacture.
Where appropriate take adequate protection measures (e.g. SBS validation).
Provide information for safety and where appropriate training to users e.g. IFU.
The implementation and verification of the risk control measures, e.g. the information was clearly defined in IFU; training for operators; the sterilization validation was performed; sterilization control WIs, including parameters were established; etc.
The assessment of the acceptability of any residual risk(s)
Risk / benefit assessment.

CONCLUSION

Basing on the evidence seen above, the process used in production and service were found to be appropriately controlled, monitored, and operated within specified limits and documented in the product device master record and device history records. Risk control measures identified by the company in [pFMEA] for [injection molding process, extrusion molding process, EO sterilization process, primary packaging process, assembling process, etc.] were checked for implementation.
The activities and the process audited are deemed to be in conformity with the audit criteria.

Follow-up items from previous audits/ assessments:

None

Follow-up of SCN:	None			
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.			
Nonconformities:	Major:	0	Minor:	0
Observations:	None			
Follow-up items for the next audit	None			

4.4.2 Infrastructure, monitoring and measuring equipment.

(ISO 13485:2016: 6.3, 6.4, 7.6; ISO 9001:2015 / ISO 15378:2017: 7.1)
(EU MDR: no specific requirements)

Audited area / organizational unit:	Production dept. Quality dept.	**Location(s) audited:**	2,3
Method of audit evidence collection:	Reported by RL Site 2,3 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities		
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	**INFRASTRUCTURE** The organization has established requirements for the infrastructure of its manufacturing facility to ensure that buildings, utilities, and space allow products to meet specified requirements. The following utilities are available at the audited location: air treatment, water treatment, compressed gases, injection molding, machines, extrusion molding machines, EO sterilization chambers, etc. Those utilities are validated, maintained and monitored in accordance with [infrastructure control procedure # MDL-QP-6.3, rev. D/1]. **Sampling rationale:** Directly impact the ability of the device to meet its essential design outputs. Site 2: extrusion molding machine, equipment no.: LG01 Site 3: EO sterilization chamber, equipment no.: MJ05 **Documents and records reviewed:** Site 2: Extrusion molding machine maintenance SOP # MDL-QS-6.3-15, maintenance items, periods, etc. were defined. Maintenance plan # MDL-QR-6.3-02 was available. Daily maintenance record # MDL-QR-6.3-06 for 2024-06 was available. Monthly maintenance record # MDL-QR-6.3-07 for Y2024 was available. Site 3: EO sterilization chamber maintenance SOP # MDL-QS-6.3-15, maintenance items, periods, etc. were defined. Maintenance plan # MDL-QR-6.3-02 was available. Daily maintenance record # MDL-QR-6.3-06 for 2024-06 was available. Monthly maintenance record # MDL-QR-6.3-07 for Y2024 was available. **MME CONTROL** The organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. It was verified that the monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results. It was also confirmed that the organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected.		

	Sampling: Directly impact the ability of the device to meet its essential design outputs. **Records / audit trail:** Monitoring and measuring equipment control procedure # MDL-QP-7.6, rev. D/1 was established and performed according to the EN ISO 13485:2016, the responsibility and workflow was specified clearly, e.g.: quality dept. was responsible for process control of calibration. Monitoring and measuring equipment lists # MDL-QR-7.6-01 for site 2 and site 3, the equipment name, specification, calibration number, manufacturer, etc., has been recorded in detail. Site 2: Equipment ID: YQ43 Date last Calibration: 2023-11-28 Calibration due: 2024-11-27 Cycle: once a year Equipment Name: Gas chromatograph SN: JL23181-045841 Model ID: JQ-7900 Calibration company: Jiangsu Zhongke Measurement & Testing Research Co., Ltd. (CNAS L12059) Internal calibration instruction: NA Site 3: Equipment ID: YQ24-3 Date last Calibration: 2024-05-22 Calibration due: 2025-05-21 Cycle: once a year Equipment Name: Vernier caliper SN: JL24195-020342 Model ID: (0~25)mm Calibration company: Jiangsu Zhongke Measurement & Testing Research Co., Ltd. (CNAS L12059) Internal calibration instruction: NA No out of calibration measuring device happened.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.4.3 Work environment and contamination control.

(ISO 13485:2016: 6.4, 7.5.2, 8.2.6; ISO 9001:2015 / ISO 15378:2017: 8.5.1)
(EU MDR: no specific requirements)

Audited area / organizational unit:	Quality dept.	**Location(s) audited:**	2,3
Method of audit evidence collection:	Reported by RL (for site 2) and CQ (for site 3) Site 2, 3 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities		

Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):

The organization has established requirements for product cleanliness which include:

- [temperature, humidity, total particle counts, microbial counts, bio-burden, etc.]

The organization has established, implemented, and maintains a process for contamination control. This was assessed by reviewing:

- [Work environment and contamination control procedure # MDL-QP-6.4, rev. D/1] which establishes requirements for health, cleanliness, and clothing of personnel that could adversely affect product quality
- [Work environment control contamination procedure # MDL-QP-6.4, rev. D/1] which establishes requirements for monitoring and controlling [ISO class 8 clean room] that could adversely affect product quality.
- The organization performs the production process steps [injection molding process, extrusion molding process, assembling process, primary packaging process] in clean room class [ISO class 8 clean room]
- Training records for personnel working under [ISO class 8 clean room] was available.
- [Work environment control contamination procedure # MDL-QP-6.4, rev. D/1] which establishes requirements for controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel

Records reviewed:

All clean rooms in site 2 and site 3 were monitored through clean room monitoring SOP # MDL-QS-6.4-01, rev. D/1.

For clean room control (site 2)

- Clean room qualification report: air exchange rate test record # MDL-6.4-12-1; airborne particle test record # MDL-QR-6.4-10-1; microorganism test record # MDL-QR-6.4-11, etc.
- Monitoring frequency: for air exchange rate was tested monthly; for microorganism was measured weekly; for airborne particle was monitored every three months.
- Differential pressure implemented: ≥ 10Pa
- Particle count limit: ≥ 0.5μm, ≤ 10,500,000pcs; ≥ 5μm, ≤ 60,000pcs
- Bacterial count limit: ≤ 10cfu/dish
- Monitoring dates: 2024-06-10.
- Results within the limit: for extrusion molding workshop, microorganism average 1cfu/dish; airborne particle ≥ 0.5μm, 49,705pcs; ≥ 5μm, 2120pcs; air exchange rate, 39times/h.

For clean room control (site 3)

- Clean room qualification report: air exchange rate test record # MDL-6.4-12-1; airborne particle test record # MDL-QR-6.4-10-1; microorganism test record # MDL-QR-6.4-11, etc.
- Monitoring frequency: for air exchange rate was tested monthly; for microorganism was measured weekly; for airborne particle was monitored every three months.
- Differential pressure implemented: ≥ 10Pa
- Particle count limit: ≥ 0.5μm, ≤ 10,500,000pcs; ≥ 5μm, ≤ 60,000pcs
- Bacterial count limit: ≤ 10cfu/dish
- Monitoring dates: 2024-06-13.
- Results within the limit: for injection molding workshop 1, microorganism average 1.5cfu/dish; airborne particle ≥ 0.5μm, 1,197,194pcs; ≥ 5μm, 4021pcs; air exchange rate, 24times/h.

A pest control program has been established in [preservation of pest and mouses SOP # MDL-QS-6.4-12, rev. D/1]. Pest control records show that the pest control activities are performed according to the program. The organization has evaluated chemicals used in pest control for their impact on product quality. The organization has established housekeeping procedures and schedules for production areas. The auditor visited [production workshops and warehouses] and verified that housekeeping activities are documented. The area was found to be clean and no pests were observed.

	Records reviewed: Site 2: During the visit to the finish product warehouse, No. 21 mouse trap was found in place, which complies with the provisions of the pest control layout plan. Site 3: During the visit to the finish product warehouse, No. 30 mouse trap was found in place, which complies with the provisions of the pest control layout plan.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.4.4 Validation of processes and software. Validation of sterilization and sterile barrier systems

(ISO 13485:2016: 4.1.6, 7.5.6. 7.5.7; ISO 9001:2015 / ISO 15378:2017: 8.5.1)
(EU MDR: no specific requirements)

Audited area / organizational unit:	Production dept.	**Location(s) audited:**	2,3
Method of audit evidence collection:	Reported by GL Site 3 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities		
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	**VMP and process validation** Validation requirements for the manufacturing process for the in-house EO sterilization and primary package sealing process were checked. The Manufacturer identified the following processes to be validated: • In-house EO sterilization process • Primary package sealing process Records of the qualification of the following equipment used in the validation were reviewed: • In-house EO sterilization process equipment #MJ-04 HMG-A-60 m^3 • Primary package machine #BZ24, mold #XS62 Equipment was installed and maintained as per process qualification control procedure #MDL-QP-7.5.6 D1. -Operators were qualified. -test methods were also subject to validation, e.g. for peel strength testing of primary package ,the peel speed and angle were validated in accordance with ISO 11607 and YY/T0681.2. It was confirmed that methods of validation have regard to the generally acknowledged state of the art. **Records reviewed:** **Validation of Sterilization process** The Organization sterilizes its products with the following methods: • EN ISO 11135:2014		

The sterilization is performed in-house and the process was validated in accordance with the standard ISO 11135:2014.
Records from the re-validation were assessed; it could be confirmed that the relevant processes were validated in accordance with the generally acknowledged state of the art (applied standards) and that the validated processes demonstrated the achievement of a SAL of 10^{-6} .

Sampling rationale:
There were 3 sterilizers in organization, among them, 2 at site 2 and 1 at site 3. The validation and routine control at both sites were same. The sterilization validiton and routine control activity at site 3 were sampled in this audit.

Sterilization validation

- In-house
- Validation plan: NA
- Revalidation report: MDL-YZ2024-MJ01 2024.02.08
- Sterilization chamber: #MJ-04 HMG-A-60 m^3
- Cycle identification: One fractional cycle, three half cycles and two full cycles
- Validation method applied: Half cycle
- Main processing parameters applied:

Stage		Set	Tolerance
The minimum temperature of product		-	≥ 5 °C
Pre-heating	T (°C)	50	±3
Vacuum	Time (min)	-	≥60
	Depth	-25	±1
	Time (min)	10	±1
	Hold time (mins)	10	±1
Conditioning	Steam injection%	-	30~80
	Injection time (min)	5	±1
EO injection	Pressure (Kpa)	-	-25~-30
	EO gas temperature(°C)	-	15~60
	Pressure (Kpa)	35	±5
	EO mass (Kg)	40	±1
	Time (min)	-	Fixed
Exposure	T (°C)	50	±5
	Time (min)	480	±1
	Air circulation	-	Normal
Flushing	Vacuum depth(Kpa)	-5	±1
	Vacuum time (min)	-	Fixed
	Flushing time (min)	70	±10
	Flushing times	5	5
Aeration	Under nature condition	-	≥7 days

-Applied method: EN ISO 11135:2016
-Maxium bioburden allowed:≤100CFU/device
-Product family covered by the validation:Nerve Block Needles (Anesthetic Needles), Disposable Insulin Syringes, Disposable Syringes, Three-way Stopcocks, Auto-disable Syringes, Surgical Blades etc.

IQ (Installation requalification), OQ (Operational requalification) and PQ (Performance requalification) were conducted in this revalidation.

- IQ (Installation requalification)

In IQ:
-The document review(inlcude installation instructions, system chart, IFU and maintenance instructions etc) were verfied.
-The working environment, explosion-proof and storage enivonment of EO gas were verfied.
-The completeness of systems (e.g. control system, water supply system, electric supply system, vapor system and gas treatment etc) were verfied.
-The fucntion of electrical system was verfied.
-The computer and software system was verfied, including process control, screen display, softwere operation, data collection and storage and data printing etc.
-The calibration of measurement equipment was verfiied.

- OQ (Operational requalification)

-Alarm system performance and the shutdown functions if the value was beyond the set value was verifed.
-Leakage under postive and negative pressure (+60 Kpa and -50 Kpa).
-The vacuum rates of -15 Kpa within 6min and -50kpa within 30 min were verified.
-Steam injection was verfied.
-Temperature distribution on wall and throughout chamber were verfied within ±3°C.

- PQ (Performance requalification)

Total one fractional cycle, three half cycles and two full cycles were ran in this requalification.
-Product family and master products: The product family include Syringes, Three-way Stopcocks and blade etc. The master product of syringe (type 30 G) was selected basis of the analysis of mateiral, construction, bioburden and pacakge etc. This master product represent the most difficult sterilization device in this product family.
-Load configration: Loading mateiral was syringe material of PP and pacakge. There was total 16 pallets, 20 cartons for each palleter. The size of carton was 62.5*59.5*29.5cm. Total loading volume was 35m^3.
-BI: BI from Hangzhou future company was used which comply with EN ISO 11138.
-IPCD: BIs were placed in the tube of syringe where was considered the most sterilization spot in device and then packaed to make IPCD.
-EPCD: BIs were placed in PE bag and sealed and then packed to make EPCD.

Total one fractional cycle, three half cycles and two full cycles were ran in this requalification.
-One fractional cycle: Total 70 IPCD/70EPCD and 70 products were exposed to a fraction cycle (exposure time 180 min). The exposed products and BIs were subjected to sterility test according to EN ISO 11737-2. Incubation time was 7 days. The resistance comparison result: EPCD (positive rate 25.7%) ≥IPCD (positive rate 17.1%) ≥ product(positive 0)
-Fractional cycles: Each 70 IPCDs/30EPCDs were exposed to each of three half cycles (exposure time 240min). BIs were subjected to sterility test according to EN ISO 11737-2. Incubation time was 7 days. There was no growth. The SAL was demonstrated.
-Full cycles: Each 55 temperature & RH sensors were placed in product and 30 EPCDs was attached to the outer of cartoons and exposed to each of full cycle (480min). BIs were subjected to sterility test according to EN ISO 11737-2. Incubation time was 7 days. There was no growth. The temperature and RH sensors were taken out to read. The relationship of temperature & RH distribution in load with temperature & RH probes were established and the tolerance of temperature and RH in load at each stages were established, e.g. during exposure phrase:

- The lowest temperature was 51.3 °C and the highest temperature was 52.9°C and the tolerance was set at 45~50°C.
- The lowest RH in load was 43.2% and the highest RH in load was 63.7% and the tolerance was 30~80%.

In addition:
►The parameters of temperature, HR and pressure on chamber were within the defined tolerance. The realizability and producibility of process was demonstrated.
►The EO residual was 1.7 ppm after 7 days' aeration under natural condition which was within tolerance of ≤ 10 ppm.

Routine sterilization
Records of the sterilization load No 240625 for disposable safety syringe were checked during the audit. It was confirmed that the applied sterilization conditions are consistent with the conditions validated as explain above.

It was confirmed that the sterilization process is validated, periodically re-validated, and records of the validation are available, that devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions, and that the sterilization process and results are documented and traceable to each batch of product.

Records reviewed:
Packaging and sterile barrier systems validation:

- Validation report: MDL-YZ2024-XBZ16
- Equipment used: package machine #BZ24, mold #XS62

	• Validated process parameters (nominal conditions): Formation temperature (85~115°C), Heating temperature (123~153°C), Gas pressure (0.4~0.6Mpa) • Packaging material: Glued porous paper + PE complex film • Products covered by the validation: Safety syinge etc • Applied standards: EN ISO 11607 IQ (Installation requalification), OQ (Operational requalification) and PQ (Performance requalification) were conducted. • IQ (Installation requalification) IQ(Installation requalification) was conducted. The equipment installation, function and calibration were verified. • OQ (Operational requalification) OQ (Operational requalification) was conducted. The formation temperature and heating tempereature was set at the extreme values and the appearance, seal width, peel strength (≥1.5N/15mm) and seal intergrity (dye penetration) were verfied. • PQ (Performance requalification) Consecutive batches, 13 samples for each batch, were sampled. The formation temperature and heating tempereature was set at the normal values, i.e., formation temperature (100°C), Heating temperature (138°C), the appearance, seal width, peel strength (≥1.5N/15mm) and seal intergrity (dye penetration) were verfied. **VALIDATION OF PRODUCT REALIZATION SW** It was verified that the software used in the production of EO sterilization was validated for its intended use in accordance with planned arrangements. Traceability of the test equipment calibration was confirmed. Software validation was performed during equipment qualification. **Records / audit trail:** Revalidation report: MDL-YZ2024-MJ01/IQ (Installation requalification)/Computer and software system verification
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.4.5 Control of nonconforming product

(ISO 13485:2016: 8.3; ISO 9001:2015 / ISO 15378:2017: 8.7, 10.2)
(EU MDR: no specific requirements)

Audited area / organizational unit:	Quality dept. **Location(s) audited:** 2,3
Method of audit evidence collection:	Reported by RL (for site 2) and GL (for site 3) Site 2,3 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed	The Organization adequately identifies, controls, and disposes of nonconforming products. These actions are based on the risk the nonconformity poses to the device meeting its specified requirements. It was verified that any adverse effects of rework activities are reviewed and documented on [# MDL-QR-8.3-01], and that rework processes are performed per

(identify site audited and auditor initials):	[Nonconforming product control procedure # MDL-QP-8.3, Rev. D/1]. These rework procedures are approved before rework is initiated. Results of the rework are reviewed and final approvals are documented to verify that the product conforms to the requirements. This review and final approval confirms the Organization has determined if there is an adverse effect of the rework on the product and conforms to the requirements. **Documents and Records reviewed:** Communication with the organization, the nonconformity only came from IPQC on site 2. No NC on site 3. The process was similar, so one of them was sampled. NC Record # MDL-QR-8.3-01, NO. 20240428011 Opened: 2024-04-28 Status: closed Issue: The tip of the needle (no.240420-2271, quantity: 4500pcs) punctured the sheath. Risk: Product damage Correction/Decision: Select and use Corrective Action: Train employees.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.4.6 Customer related processes

(ISO 13485:2016: 5.2, 7.2; ISO 9001:2015 / ISO 15378:2017: 7.1, 8.2)
(EU MDR article 10(12))

Audited area / organizational unit:	Sales dept. **Location(s) audited:** 2
Method of audit evidence collection:	Reported by CQ Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	It was confirmed that the medical device organization performs a review of the customer's requirements, including the purchase order requirements, prior to the medical device organization's commitment to supply a product to a customer. It was verified that the medical device organization maintains documentation required by regulatory authorities regarding maintenance of distribution records. **Documents and Records reviewed:** The following examples of orders and distribution records were reviewed: PO#:MDL-QR-7.2-04, NO. 20231114 Date: 2023-11-14 Country: Saudi Arabia Date of shipment: 2024-03-12 Supply contracts were divided into conventional contracts and special contracts. Special contracts are subject to internal review. The manufacturer communicates with their customers by email, fax, phone call and visiting through the brochure, the exhibition and

	the website, customer visiting etc. Products are mainly sold abroad. One of special order was checked, as followed: • One domestic sales order # MDL-QR-7.2-04, NO. 220231114, between manufacturer and Terumo Corporation, which signed on 2023-11-14 was checked which include: product name (Disposable Syringes), and model quantity, price, delivery requirement, etc. • The contract reviewed # MDL-QR-7.2-03 performed by Sales department, PMC department, production department, quality department and technical department. Review items include: package identification integrity, raw materials, product characteristics, etc., the contract review records finally approved by GM on 2023-11-14. • No advisory notification or product recall has happened since last audit, but the related procedures for communication with regulatory authorities were established, e.g., Feedback Control Procedure # MDL-QP-8.2.1 Rev D/1; Complaint Control Procedure # MDL-QP-8.2.2 Rev D/1; Advisory Notices Release Control Procedure # MDL-QP-8.2.3-01 Rev D/1;Product Recall Control Procedure # MDL-QP-8.2.3-02 Rev D/1; Adverse Events Monitoring Control Procedure # MDL-QP-8.2.3-03 Rev D/1; and Vigilance System Control Procedure MDL-QP-9.7 Rev D/1 were established.
Follow-up items from previous audits/ assessments:	None
Follow-up of SCN:	None
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.
Nonconformities:	Major: 0 Minor: 0
Observations:	None
Follow-up items for the next audit	None

4.4.7 Installation and servicing activities

(ISO 13485:2016: 7.1, 7.5.3, 7.5.4,; ISO 9001:2015 / ISO 15378:2017: 8.5.1, 8.5.2)
(EU MDR: no specific requirements)

The requirements have not been audited due to:

☒ they are excluded or non-applicable for the QMS

☐ they are not planned to be audited based on audit programs, following conditions are met:

- the requirements were audited during the previous audit
- no nonconformity to these requirements from the previous audit
- no significant change in the process

4.5. Purchasing

(ISO 13485:2016: 7.4; ISO 9001:2015 / ISO 15378:2017: 8.4)
(EU MDR article 10(9))

Audited area / organizational unit:	Purchasing dept **Location(s) audited:** 2
Selected supplier and rationales for the selection	**Selected supplier(s) evaluation file:** purchasing control procedure # MDL-QP-7.4, Rev. D/1. Rationales for the selection: ☐ indications of problems with supplied products or processes from audit of the Measurement, Analysis and Improvement process ☐ suppliers of higher risk products or processes ☒ suppliers who provide products or services that directly impact the design outputs required for proper functioning of the device ☐ suppliers of processes that require validation or revalidation

Method of audit evidence collection:	☒ newly approved suppliers of products or services ☒ suppliers of products or services used in the manufacturing of multiple products ☒ suppliers of components or services not covered during previous audits ☐ other: Reported by CQ Site 2 audited on-site **Method of audit evidence collection**: ☒ interview with auditee ☒ review of documents and records ☐ observation of process and activities
Activities and processes evaluated, documents and records reviewed (identify site audited and auditor initials):	**Supplier selection / evaluation / re-evaluation** It was verified that suppliers are selected for use by the organization based on their ability to supply product or services in accordance with the organization's specified requirements. The degree of control applied to the supplier(s) is commensurate with the significance of the impact of the supplied product or service on the quality of the finished device, based on risk. The following suppliers were selected for assessment: Supplier 1 - Daoen Group Limited Applied criteria 1. Direct impact to essential design outputs 2. Newly approved 3. Used in multiple products Supplier 2 - Wenzhou Jinghuan Technology Co., LTD Applied criteria 1. Direct impact to essential design outputs 2. Used in multiple products 3. Not covered during previous audits **Documents and records reviewed:** The qualified supplier list # MDL-QR-7.4-05 (including class A & class B & class C) issued date: date on 2024-02-23 was updated and checked. Two new suppliers was added (Daoen Group Limited and Shanghai Weisu electronic Commerce Co., LTD, who provides plastic particles. So the supplier with the largest purchase volume was sampled). Supplier for plastic particles —Daoen Group Limited: • Supplier questionnaire # MDL-QR-7.4-01, no. A68, the items included the basic information of the supplier, production characteristics, main production inspection equipment, etc. dated on 2024-02-18. • Small batch trial tracking table # MDL-QR-7.4-11, no. A68, the result was positive on 2024-02-20. • Supplier evaluation form # MDL-QR-7.4-02, no. A68, dated on 2024-02-20, decide as class A qualified supplier, including the quality performance, QMS, performance review, showed that It is qualified. And the conclusion is positive and the supplier was added in qualified supplier list. • Quality agreement # MDL-QR-7.4-06, NO. A68, signed on 2024-02-20, the quality requirements, documentation control, acceptance criteria, performance evaluation, IQC, NC product handling, etc. were specified and deemed acceptable. Supplier for needle —Wenzhou Jinghuan Technology Co., LTD • Quality agreement # MDL-QR-7.4-06, NO. A46 signed on 2022-04-20; the articles such as the responsibilities and authorities of the quality capacity, quality standard, acceptance criteria, quality issue handling, change management, continuous improvement, claim, complaints, delivery, supplier

assessment and auditing etc. were clearly defined, deemed to fulfill the requirements.
- Supplier re-evaluation form # MDL-QR-7.4-03, dated on 2024-01-09, decide as class A qualified supplier, including the quality performance, QMS, performance review, the score was 93 and showed that It is qualified. And the conclusion is positive and the supplier was kept in qualified supplier list.
- QMS certificate under EN ISO 13485: 2016, certificate no.: Q6 091403 0003, Rev. 01 issued by TUV SUD valid until 2024-08-16; the purchased product non-woven fabrics was covered.

Purchasing requirements and orders
It was verified that procedures for ensuring purchased product conforms to purchasing requirements have been established and documented.
The Organization has defined the purchasing requirements in product specifications. The records seen demonstrate that the purchased product complies with the corresponding purchasing requirements.

It was confirm that the medical device organization ensures the adequacy of specified purchase requirements prior to their communication to the supplier and that a written agreement with the supplier is established in which suppliers has to notify the medical device organization about changes in the product. This was confirmed in the agreement dated 2024-02-20 with Daoen Group Limited and dated on 2022-04-20 with Wenzhou Jinghuan Technology Co., LTD.

It was verified that the medical device organization documents purchasing information, including where appropriate the requirements for approval of product, procedures, processes, equipment, qualification of personnel, and other quality management system requirements.

It was confirmed that documents and records for purchasing are consistent with traceability requirements.

Documents and records reviewed:
- One purchasing order no.: MDL-ZG-JH-20240220 was sampled and checked, dated 2024-02-20, regarding the needle, model: 0.3*23mmRWLB, quantity: 500000 pcs, the detailed product information, delivery, payment, COA, etc., the purchasing process was demonstrated.
- One purchasing order no.: XSHT240307005 was sampled and checked, dated on 2024-03-28, regarding the PP-R, model: RP340R, quantity: 66 000 kg, the detailed product information, delivery, payment, COA, etc., the purchasing process was demonstrated.

Verification of purchased products
It was confirmed that the verification (inspection or other activities) of purchased products is adequate to ensure specified requirements are met.

It was confirmed that the medical device organization has implemented an appropriate combination of controls applied to the supplier, the specification of purchase requirements, and acceptance verification activities that are commensurate with the risk of the supplied product upon the finished device.

It was verified that records of verification activities are maintained.

Documents and records reviewed:
For needle: IQC for needle (Critical raw material), lot: T240305-1:
- WI # MDL-QS-8.2.6-01, Rev. D/1.
- IQC report # MDL-QR-8.2.6-14-09, dated on 2024-03-01, inspection record for material of needle, lot # T240305-1, 500000 pcs, concerning appearance, size, rigidity, toughness, initial contamination bacteria etc., according to WI # MDL-QS-8.2.6-01, Rev. D/1,the conclusion is pass.
- COA # JK/ZJ003-7, dated on 2024-03-02, was available.

	For PP: IQC for PP (Critical raw material), lot # T240401-1. • WI # MDL-QS-8.2.6-01, Rev. D/1. • IQC report # MDL-QR-8.2.6-14-06, date on 2024-04-01, inspection record for material of PP, lot # T240401-1, 66000 kg, concerning size, appearance and package, according to WI # MDL-QS-8.2.6-01, Rev. D/1.,the conclusion is pass. • COA # 20240217901B, was available.			
Follow-up items from previous audits/ assessments:	None			
Follow-up of SCN:	None			
Statement concerning compliance	The activities and the process audited are deemed to be in conformity with the audit criteria.			
Nonconformities:	Major:	0	Minor:	0
Observations:	None			
Follow-up items for the next audit	None			

5. References

Audit plan