Amcor – Peosta, IA

We are a Packaging component Manufacturer – No drugs, drug components of finished Pharmaceutical product.

Please contact your sales Representative or Customer Service Representative concerning Regulatory inquiries.

This Document is provided to answer the most frequently asked questions listed on the questionnaires of Customers seeking to Audit the Peosta facility.

Corporate Headquarters:

Full Street Address: Amcor
101 Oakley Street
Evansville, IN 47710
www.amcor.com

Manufacturing Site:

Full Street Address Amcor
19101 Kapp Drive
Peosta, IA 52068
Telephone Number: 563-588-4031
Facsimile Number: 563-588-1463

Age of Building: 39 Years

Square Feet of all buildings total: 181,000

MANUFACTURER OF: Plastic molded bottles

KEY PERSONNEL:
See last page

Contact Personnel:

Position/Title	Name	Phone Number	E-mail
Plant Manager	**Kevin Gudenschwager**	**x 2414**	kevingudenschwager@amcor.com
Quality Assurance Manager	**Brenda Hein**	**x 2433**	**brendahein@amcor.com**
SQF Practitioner	**Brenda Hein**	**X 2433**	**brendahein@amcor.com**
Production Manager	**Donna Kemler**	**X 2455**	donnakemlerr@amcor.com

Number of Staff Employed: 114

Shifts: ☒ 1st ☒ 2nd ☒ 3rd ☒ 12 Hour

On average this site runs 24 hours per day and 7 days per week.

PERSONNEL

Has there been any change to the following elements: Standards, Organization of Quality Unit, and Ratio of Quality Unit Staff to Production Staff?

Answer: No

	QUALITY MANAGEMENT SYSTEM (QMS)	ANSWER
1	Is there a Quality Manual (QM)?	Yes
2	Does the QMS contain a Quality Policy?	Yes
3	Does the QM define the responsibility and authority of all employees?	Yes
4	Does the QM give the Quality Unit authority to review records and conduct investigations?	Yes
5	Is there a periodic review of the QM and QS required? If so, how often?	Yes
6	During the past three (3) years, has the facility been involved with "Quality Management Systems", either ISO 9000 or an equivalent system?	Yes

Details of the past three (3) years				
Registration Body	**Inspection Date(s)**	**Certification**	**Certification Granted**	**Certification #**
Eagle Registration	9/15/2024	ISO 9001:2015	N/A	4255 AC
Eagle Registration	12/26/2024	SQF Code Ed. 9	N/A	12801

	FOOD SAFETY SYSTEM (FSS)	ANSWER
1	Is there a documented food safety program?	Yes
2	Is there a documented Food Safety Policy?	Yes
3	Does the FSS define the responsibility and authority of all employees?	Yes
4	Does the FSS give the Quality Unit authority to review records and conduct investigations?	Yes
5	Is there a periodic review of the FSS required? If so, how often?	Yes twice a year
6	Is there a documented food safety plan?	Yes
7	Is there a documented allergen program?	Yes
8	Is there an environmental monitoring program? (List environmental factors that are monitored and how often)	Yes
9	Is there a documented traceability program?	Yes

10	Is there a GMP Program in place?	Yes
11	Is there a complete food safety risk assessment?	Yes
12	Is there as documented sanitation program?	Yes
13	Are raw materials stored separate from finished product?	Yes
14	Is there a documented trace program?	Yes
15	Is there documented maintenance and Preventative maintenance programs?	Yes
16	Is there a documented food defense plan?	Yes
17	Is there a documented crisis management plan?	Yes
18	Is there a documented food fraud program?	Yes
Details of the past year		

	INDEPENDENCE/AUTHORITY/TRAINING	**ANSWER**
1	Is Quality Assurance independent of Manufacturing?	Yes
2	Does QA/QC have independent authority to approve and reject materials (raw materials, components and finished goods)?	Yes
3	Is there a documented training program including GMPs?	Yes
4	Is there a means for verifying trainee competency?	Yes
5	Do GMP training materials address facility cleaning, personal hygiene and record keeping?	Yes
6	Do employees practice good hygiene in the manufacturing operations?	Yes
7	How do you assure that departmental staff are trained to follow new versions of documents (procedures, batch records, test methods, etc.)?	Completed training records
8	Briefly describe the Company's Training Program:	Monthly Communication meetings, Amcor University, Annual refresher training, new hire training and orientation, monthly quality meetings.
9	Are job specific training relevant to tasks to be performed?	Yes

	INTERNAL AUDITS/CAPA	**ANSWER**
1	Is there a documented written procedure for conducting internal audits?	Yes
2	Are internal audits being conducted according to the procedure?	Yes
3	Are responses to the audit findings/observations in the form of corrective and/or preventative actions (CAPA) addressing root cause?	Yes
4	Is there a follow up to determine if the appropriate CAPA has been completed?	Yes
5	Does QA conduct a documented review of production batch records?	Yes

	COMPLAINT HANDLING	ANSWER
1	Is there a written procedure for handling Customer Complaints?	Yes
2	Are each complaint/event uniquely identified?	Yes
3	Does the procedure require that the complaint be resolved/investigated within a specific timeframe?	Yes
4	Does the investigation involve a review of the batch records for the product related to the complaint?	Yes
5	Are samples examined or tested as necessary during a complaint investigation?	Yes
6	Is there a program in place for recording, tracking and resolving customer complaints?	Yes

	FAILURE/DEVIATION INVESTIGATIONS	ANSWER
1	Is there a documented procedure regarding the investigation of the finished products, raw materials or components which fail to meet required specifications?	Yes
2	Are investigations completed within a reasonable timeframe?	Yes, when possible
3	If necessary, do investigations include a review of production events which may contribute to or be the cause of the failure?	Yes
4	What is the timeframe?	Yes, when possible
5	Do all of the investigations include an actual or probable cause for failure?	Yes
6	Are corrective actions being implemented when the root causes have been identified?	Yes, when possible
7	Does Quality Assurance conduct or adequately review the failure investigations?	Yes
8	How do you handle OOS results?	Yes, when possible
9	In the past twelve (12) months, on how many occasions have you had an OOS result?	Yes
10	Who is responsible for the investigation reports?	Yes, when possible
11	Are investigation reports extended to other batches/lots of the same product?	Yes

	CHANGE CONTROL	ANSWER
1	Are SOPs written identified and approved for compliance?	Yes
2	Are SOPs reviewed periodically to ensure their applicability to actual practices? What is the timeframe for review?	Yes
3	Are change control procedures in place?	Yes
4	Will you notify the Customers of changes to manufacturing or materials prior to such changes being implemented?	Yes
5	Are changes relating to manufacturing/packaging processes and or equipment adequately approved where necessary?	Yes

	RECALLS/RETURNS	ANSWER
1	Is there a written procedure for conducting a recall?	Yes

2	Does the procedure require conducting mock recalls or some other means to verify the adequacy and effectiveness of the procedure?	Yes
3	Do you perform mock recalls?	Yes
4	Describe your recall procedure:	PEOSPCD-0050
5	Does the summary recall report indicate that the manufacturer was able to account for the distributed product?	Yes
6	Describe the company's procedure for handling returned goods:	Issue returned goods authorization, follow nonconforming procedure
7	Is there evidence that the returned products are being processed according to the procedure?	Yes

	VALIDATION	**ANSWER**
1	Is there a Process Validation Master Plan?	Yes
2	Does the plan require there to be an approved process validation protocol developed for each product?	Yes
3	Does validation reporting provide evidence that the study is conducted per protocol and the process is consistent?	Yes
4	Are deviations to the approved protocol appropriately documented and approved by QA?	Yes
5	Does the Validation Master Plan address re-validation?	Yes, when equipment is relocated or upgraded
6	Please describe your site's on-going equipment calibration and preventative maintenance programs:	PEOSPCD-00027
7	What is the scope of the validation program?	IQ/OQ/PQ
8	Is there a formal program to determine product safety?	Follow SQF Ed. 9 requirements

	FACILITIES and EQUIPMENT	**ANSWER**
1	Are there written procedures to address the maintenance of the facility?	Yes
2	What kind of security do you have to assure no entry by unauthorized personnel?	Secure entrances – passkey
3	What is the square footage of your facility?	180,000
4	What are your hours of operation?	24/7
5	How many shifts operate at your manufacturing site?	4
6	Is there a list of approved chemicals for maintaining the sanitation of the facility?	Yes
7	Is there a documented procedure regarding the receipt, handling, storage, use and disposal of chemicals, standards?	Yes
8	Is there proper segregation of hazardous materials?	Yes
9	Is the facility in acceptable structural condition to perform tasks?	Yes
10	Are there environmental controls for the building?	Yes
11	Is the design of the facility adequate to allow for smooth flow of materials and reduce potential for contamination?	Yes
12	I the lighting adequate for the building?	Yes
13	Is there a pest control program? Please describe:	Yes
14	Are the washrooms and toilets clean and in good working order?	Yes

15	Are the washrooms equipped with hot water and hand wash signs?	Yes

16	Are toilet facilities physically separated to prevent a direct opening to the manufacturing areas?	Yes
17	Is there a control system for implementing and tracking changes to equipment?	Yes
18	Does the control system take into account the need for revalidation?	
19	Is there a formal program for ensuring the qualification of all processing equipment with respect to installation, operation and performance (IQ/OQ/PQ)?	Yes
20	Is there a documented procedure for qualifying instruments (IQ/OQ/PQ)?	Yes

	CALIBRATION	**ANSWER**
1	Is equipment properly installed to allow for reasonable cleaning, maintenance and calibration?	Yes
2	Are there written procedures for ensuring the maintenance and calibration of equipment?	Yes
3	Is equipment labeled to readily identify Calibration status?	Yes
4	Are calibrations conducted per procedure and schedule?	Yes
5	Do you perform calibrations internally or by an outside source?	Both
6	Is there an effective means to quality outside contractors providing calibration services?	Independent certification, Amcor qualified supplier
7	Do outside contractors provide adequate documentation with regards to services provided?	Yes
8	Are all data (including graphs, scans, charts and calculations) maintained?	Yes
9	What is the frequency of calibrations?	6 months to 2 years

	MATERIAL SYSTEM	**ANSWER**
1	Is there a procedure for the receipt, sampling and identification of all raw materials?	Yes
2	Are all components (containers, closures, labels, IFC; and inserts) properly identified?	Yes
3	Are components and raw materials adequately quarantined until release by QA to Production?	Yes
4	Are there specifications for all components and raw materials?	Yes
5	Do the specifications include acceptability criteria for each item?	Yes
6	Is there an adequate program to ensure FIFO? What is it?	Yes
7	Are all components and raw materials being tested against appropriate and established specifications?	No, all materials are received under CoC/CoA documentation
8	Is at least one specific identity test conducted on each lot of components?	No
9	Are raw materials, in-process and finished products adequately dispositioned when failing to meet established specifications?	Yes
10	Are investigations involving NCM documented?	Yes

11	Does QA have full authority to accept or reject all raw materials and packaging materials?	Yes
12	Are finished products adequately controlled until release for shipment?	Yes

13	Is there a documented procedure for in-process materials or finished products that fail to meet the required manufacturing standards/specifications?	Yes
14	Are the investigations of the NCM being conducted in a manner per written procedure?	Yes
15	Does your company have a registered Drug Master File (DMF)?	Yes, DMF 7974
16	Describe the sampling plan for the checking, testing and release of the product:	First article and continuous in-process checks, nonconforming held in JDE, release after batch record review and NPR closed.
17	Do you supply a Certificate of Compliance or Certificate of Analysis for each batch?	Yes, when required

	VENDOR QUALIFICATION/TESTING	**ANSWER**
1	Where raw materials are not fully tested against specifications, is there a program for qualifying suppliers?	Yes
2	Does the program for qualifying suppliers include conducting audits or reliance on historical data?	Yes
3	Where historical data is used to qualify suppliers, does historical data include information on all the characteristics listed in the specifications?	Yes
4	Is there an adequate program to establish the qualifications reliability of suppliers providing raw materials if full testing is not conducted on incoming raw materials?	Yes

	PRODUCTION PROCESS	**ANSWER**
1	Is there a control system for implementing changes in process?	Yes
2	Does the control system recognize the need for revalidation before processes are changed?	Yes
3	Is there a documented procedure for the retention of batch records for each finished product manufactured?	Yes
4	Do batch production records contain the required information necessary with respect to assuring the quality of the finished product?	Yes
5	Are batch records reviewed by QA?	Yes
6	Do batch records contain instructions with respect to the manufacture of finished products?	Yes
7	If a water system is used, is it operating in the manner designed?	N/A
8	Is a record created for every lot/batch of product produced?	Yes
9	Is there a documented procedure for the retention of reserve samples for each batch of product manufactured?	Yes
10	Are periodic samples taken during the component manufacturing process to ensure that the component meets specification	Yes

	requirements?	
11	Are retain samples of raw materials, bulk product and finished goods maintained for the required period of time?	Yes

	PRODUCT ASSEMBLY and PACKAGING	ANSWER
1	Are components used in production runs checked for adequacy prior to commencing a packaging run?	Yes
2	Is line clearance documented?	Yes
3	Is QA or manufacturing personnel involved in periodically monitoring parameters (counts, torques, coding, etc.)?	Yes
4	Describe the controls utilized to assure the products are completely and accurately labeled:	QA provides label and batch record control and line clearance release
5	Are there documented procedures for ensuring the cleanliness, maintenance and calibration of equipment?	Yes
6	Describe your lot numbering system:	Eight digit sequential number generated by JDE, example: C12345678
7	Are all lines and hoppers adequately covered to prevent contamination?	Yes, when required
8	Are the lines properly identified with the name/description and lot # of the product?	Yes
9	Are there documented procedures for label control?	Yes
10	Describe procedures for labeling, segregation and control of finished product prior to final disposition:	Item Spec Sheets, batch record control and Line Clearance Procedure
11	Describe your procedure for ensuring that labels are not used until they are proofread for accuracy:	Line clearance procedure

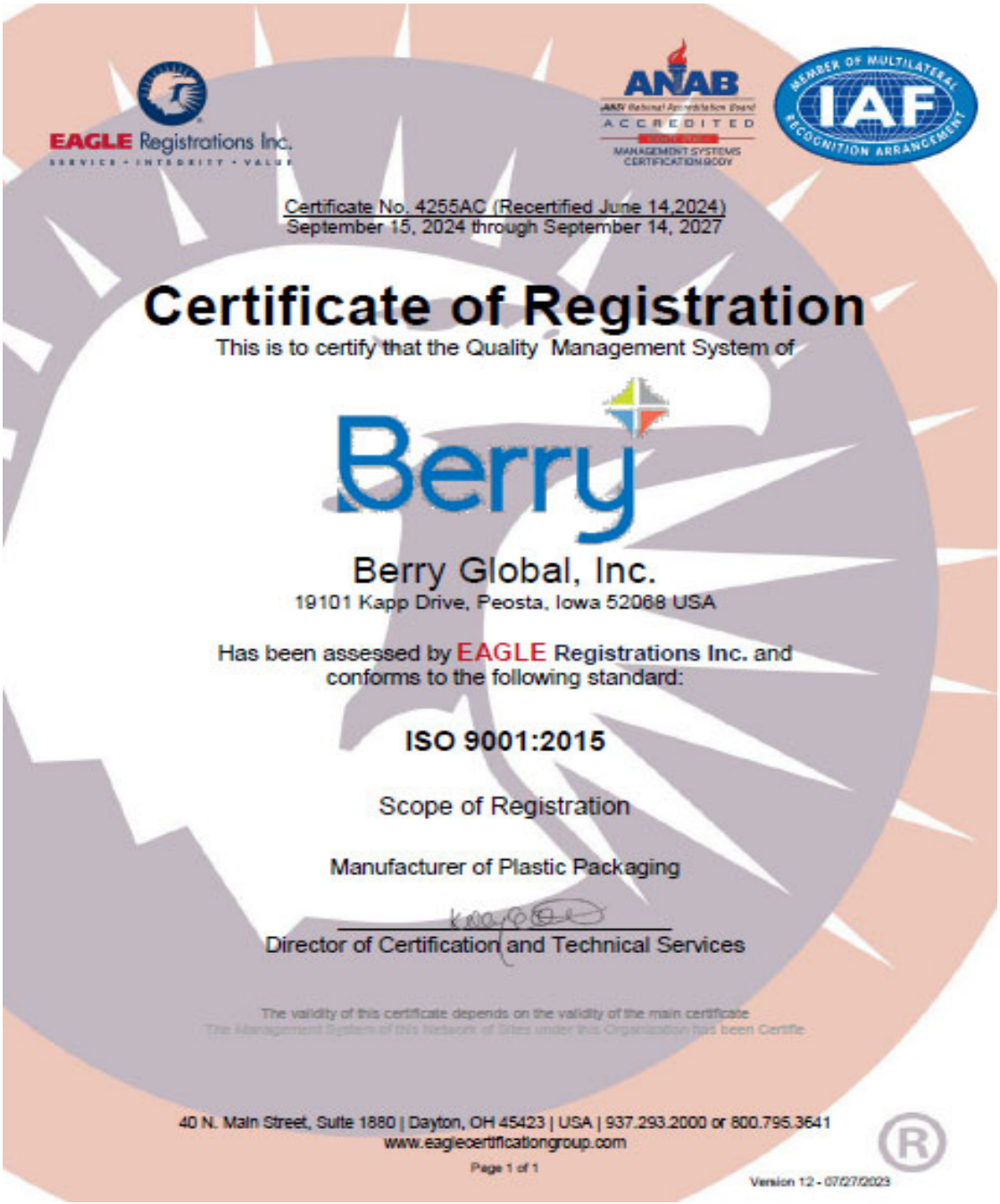
	DOCUMENT CONTROL	ANSWER
1	Is there a defined document control program in place?	Yes
2	Do controlled documents use an ID and revision level system?	Yes
3	Is there a documented procedure for Document Control including record retention?	Yes
4	How long are records kept?	7 years

Completed By: Brenda Hein

Title: QA Manager/ISO MR/ SQFP

Date: 5/6/2025

Attachments:



EAGLE Registrations Inc.
SERVICE • INTEGRITY • VALUE

ANAB
ACCREDITED
MANAGEMENT SYSTEMS CERTIFICATION BODY

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
IAF

Certificate No. 4255AC (Recertified June 14,2024)
September 15, 2024 through September 14, 2027

Certificate of Registration

This is to certify that the Quality Management System of

Berry

Berry Global, Inc.
19101 Kapp Drive, Peosta, Iowa 52068 USA

Has been assessed by EAGLE Registrations Inc. and conforms to the following standard:

ISO 9001:2015

Scope of Registration

Manufacturer of Plastic Packaging

Director of Certification and Technical Services

The validity of this certificate depends on the validity of the main certificate
The Management System of this Network of Sites under this Organization has been Certifie

40 N. Main Street, Suite 1880 | Dayton, OH 45423 | USA | 937.293.2000 or 800.795.3641
www.eaglecertificationgroup.com

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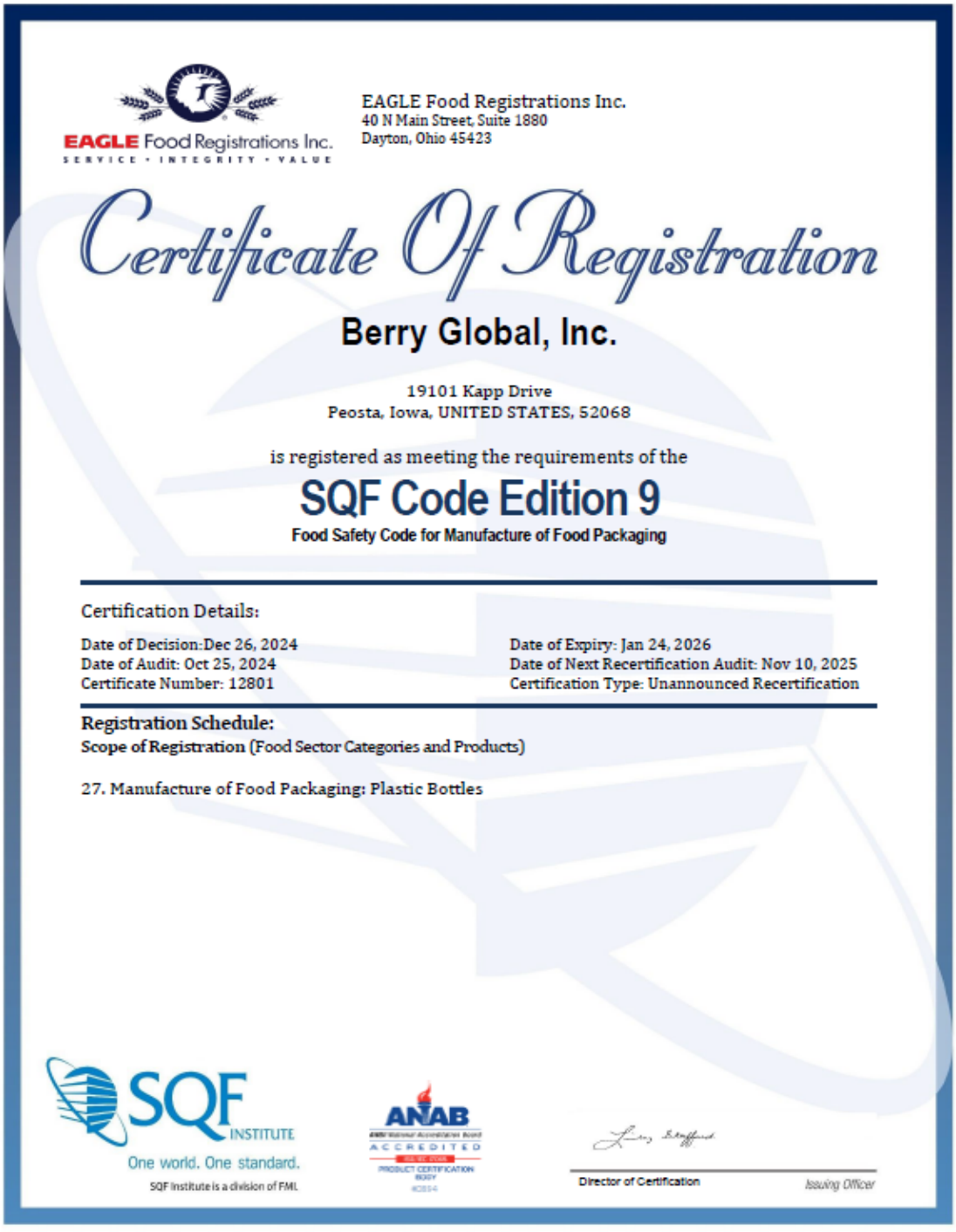

EAGLE Food Registrations Inc.
SERVICE • INTEGRITY • VALUE

EAGLE Food Registrations Inc.
40 N Main Street, Suite 1880
Dayton, Ohio 45423

Certificate Of Registration

Berry Global, Inc.

19101 Kapp Drive
Peosta, Iowa, UNITED STATES, 52068

is registered as meeting the requirements of the

SQF Code Edition 9

Food Safety Code for Manufacture of Food Packaging

Certification Details:

Date of Decision:Dec 26, 2024
Date of Audit: Oct 25, 2024
Certificate Number: 12801

Date of Expiry: Jan 24, 2026
Date of Next Recertification Audit: Nov 10, 2025
Certification Type: Unannounced Recertification

Registration Schedule:
Scope of Registration (Food Sector Categories and Products)

27. Manufacture of Food Packaging: Plastic Bottles

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SQF Institute is a division of FMI

ANAB ACCREDITED PRODUCT CERTIFICATION BODY

Director of Certification

Issuing Officer

Organizational Chart