Audit Report

Global Standard Packaging Materials Issue 6: August 2019

Audit summary			
Company name	National Flexibles Ltd	BRCGS site code	2113728
Site name	Bradford		
Scope of audit	The slitting, rewinding, hot needle perforation and core cutting, with outsourced processes of centre folding, gravure, digital and flexographic printing, lamination and die-cutting of polypropylene, polyethylene, amorphous polyethylene, terephthalate, polyamide, ionmer (Surlyn), metallised APET, OPA, EVOH, OPP, LLDPE, PVdC to produce films on the reel, pouches and lids for food products (contact)		
Scope exclusions	None		
Justification for exclusion	N/A		
Start date	2021-07-01	Finish date	2021-07-02
Re-audit due date	2022-07-01	Previous audit date	2020-01-10

Additional modules included			
Modules	Result	Scope	Exclusions from Scope
Choose a module	Choose an item		
Choose a module	Choose an item		

Audit results			
Audit result	Certificated	Audit type	Announced
Audit grade	AA	Previous audit grade	A
Certificate issue date	Select a date	Certificate expiry date	2022-08-20

Number of non-conformities		
	Major against SOI of Fundamental	0
	Critical	0
	Major	0
	Minor	2

If you would like to feedback comments on the BRCGS Standard or the audit process directly to BRCGS, please contact tell.brcgs.com

Company details

Address	2 Battlefield View, Birkenshaw, Bradford, BD11 2PT		
Country	United Kingdom	Telephone	0044 (0) 1274 685566
Commercial representative Name	Mark Thompson	Email	mark@nationalflexibles.net
Technical representative Name	Caroline Clay	Email	caroline@nationalflexible.net

Company profile

Plant size (square metres)	<10K sq.m	No. of employees	1-50	No. HARA Plans	1-3
Subcontracted activities	No				
Outsourced processes	Yes				
Other certificates held	ISO 9001:2015				
Regions exported to	Europe Choose an item. Choose an item. Choose an item. Choose an item.				
Major changes or auditor observations since last BRCGS audit	New MIS Radius system installed				
Company description	The company was established over 40 years ago and became part of the Charles Baynes group in 1993. In 1998 Barry Twigg the current chairman undertook an MBO and National Flexible has evolved into a high-quality supplier of flexible films owned by its management and staff and is located on a light industrial estate in Birkenshaw, to the south-east of Bradford. The site supplies a wide range of laminated, polypropylene, polyethylene, amorphous polyethylene Terephthalate, polyamide, metallised; APET, OPA, EVOH, OPP, LLDPE, PVdC plain and printed film primarily for UK and EU food customers. Films are purchased, the artwork process is managed in-house and printing centre fold, die cutting and lamination is outsourced to meet customers'				

Company profile	
	specific needs. The machinery on site includes slitting, rewinding and perforating equipment. Stock is held on site and called off by customers when required to give a rapid response. The site support and fund both on the job training and general interest training for all employees and have excellent staff engagement. The buildings comprise an area of 2,525 square metres. The site is entirely suited to the production and supply of food grade packaging products. There are 40 personnel operating a rotating 2-shift system and are no more than 35 staff on site at any one time. The site has developed and implemented compliance systems that meet the requirements of the BRCGS Standard version 6. Effective Covid-19 precautions are in place

Product and process characteristics	
Manufacturing Categories	05 - Flexible plastics Please select Please select Please select Please select
Products in production at the time of the audit	Printed and plain films of varying materials and sizes slit and perforated for food use

Audit duration details			
On-site duration	12 hours	Duration of production facility inspection	4 hours
Reasons for deviation	None		
Next audit type selected	Announced		

Audit Duration per day

Audit Day	Date	Start Time	Finish time
1	2021-07-01	08:35	16:40
2	2021-07-02	08:20	12:15

Auditor information		
Auditor number	Auditor Name	Role
21409	Laurence Powell	Auditor
N/A		Please select

Present at audit

Note: the most senior operations manager on site should be listed first and be present at both opening & closing meetings

Name/Job Title	Opening Meeting	Site Inspection	Procedure Review	Closing Meeting
Mark Thomson, Operations Director	x	x	x	x
Andy Burden, Operations Manager	x			x
Caroline Clay, Quality Manager	x	x	x	x
Toni Leach, QA assistant	x	x	x	x
JP, Technical Customer Champion			x	
RS, Technical Customer Champion			x	
JE, Warehouse Operator		x	x	
TB, Operator		x	x	
DH, Operator		x	x	
SH, Operator		x	x	
GJ, Operator		x	x	
CA, Operator		x	x	

GFSI Audit History		
Date	Scheme/Standard	Announced/Unannounced

Template control	PackMat	Version	1.0

Non-Conformity Summary Sheet

Major non-conformity against statement of intent of a fundamental requirement				
No.	Clause	Detail	Critical or Major	Ant. re-audit date

Critical			
No.	Clause	Detail	Ant. Re-audit date

Major							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

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Minor							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by
1	4.5.1	QM10.1 Site plan does not show routes for removal of waste or process flow	Added waste removal routes to QM10.2 Revised Site Map and SOP012.1 audit schedule	Document QM10.2 has been added to internal audit schedule, under Site Standards Section 4. To be reviewed twice a year and new audit schedule prepared to ensure no requirements overlooked .	Waste removal routes had been missed off the site map on last review of site documentation. This was an oversight.	2021-07-21	Laurence Powell
2	6.1.5	2021 Training records for Line clearance, production control and print order new design do not include the duration of training	Duration of training has been added to SOP007, SOP007.3, SOP012.1, QM010.2 SOP007.1.1, SOP7.6. and SOP012.1 audit schedule	All Company Training documents have been updated to include duration of training and added to the audit schedule for review. new audit schedule prepared to ensure no requirements overlooked	Wording Oversight when setting up new documents.	2021-07-21	Laurence Powell

Comments on non-conformities

Click or tap here to enter text.

Additional Modules/Head Office Non-Conformity Summary Sheet

Critical			
No.	Clause	Detail	Re-audit due date

Major							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Minor							
No.	Clause	Detail	Correction	Proposed preventive action plan	Root cause analysis	Date reviewed	Reviewed by

Detailed Section

1.	Senior management commitment
1.1	Senior management commitment and continual improvement

The site QM001 Quality Policy at issue 10, dated 02.09.2020 signed by the managing director incorporates site commitment of safe and legal product, regulatory compliance, continual quality improvements and is compliant with the requirements of the standard. The policy is displayed at various site locations including reception and included within the site Quality Manual. The policy is communicated to all staff on notice boards and through the staff induction program. The policy is reviewed for suitability as part of the annual management review process. There are objectives in place set at the annual Management Review meeting, held under SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020 with last annual review minutes dated 24.09.2020 and included product safety and quality targets;

- Customer Complaints <1.0% of sales orders raised, actual 2020 was 1.38%
- AA grade for BRCGS audit, Grade A in 2020
- Internal audits completed on time to schedule, achieved in 2020
- Customer complaints to be closed in 7 days, achieved 95% in 2020
- Achieve 99% in customer satisfaction survey , 98% in 2020

The Quality Manager is the dedicated BRCGS Management Representative on site the QA Assistant as the deputy. Adequate personnel and financial resources are provided at site by the senior management to ensure the standard is fully implemented. The site reviews food safety alerts and EC Legislation changes and subscribe to Packaging News, Plastics Weekly, suppliers, customers, BRCGS and www.food.gov.uk.
Products are sold within the UK and Europe and conform to legislation confirmed in site and supplier's food contact statements. External migration testing is undertaken by suppliers and included in the site statement of compliance and results are well within the migration limits laid down in the EU10/2011 directive. The site holds documentation with supporting evidence for compliance to EC legislation using a Legislation Register including, 2023/2006, EU10/2011 and 2020/1245. Statements of compliance and technical specifications are in place for all products produced at the site.
The operations director was present at the opening and closing meeting and all relevant personnel were on site and available during the assessment. The site has a system to close out non-conformities raised in internal, second-party and third-party audits, which considers root cause. Non-conformance are created from customer complaints, external audits, second-party audits, third-party audits, internal audits and are reviewed at weekly production and monthly quality meetings with attendees including the senior management. Internal non-conformance and root cause analysis is evident in the closure of the reports. Non-conformities raised at last year's audit have been effectively closed out using root cause analysis. The site has a system in place to ensure re-certification occurs on or before any future audit due date and this audit took place within the required timeframe. The BRCGS logo and references to certification status are used in accordance with the conditions of use. The site has a QM 01.2 Continuous Improvement and Food Safety and Culture Plan at issue 1, dated 25.05.2021 in place and the effectiveness of the action plan is reviewed. The site has several systems in place to engage employees and ensure continual improvement including carrying out an employee survey, staff competency evaluation, using a suggestion scheme, risk, opportunities & CI register and the site supports and funds all training both job related and general interest to broadly enhance staff skills.
Senior staff involved in the daily running of the business and daily production meetings provide the opportunity for all staff to raise any confidential concerns. All personnel had been briefed that the audit was taking place.
Viewed a genuine copy of issue 6 of the standard on site. The site has risk assessed and implemented control measures for Covid 19 including control of site visits and is reviewed evidenced in the site tour.

Audit Evidence:

Previous BRCGS Audit Report dated 10.01.2020
SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020

Genuine Copy of BRCGS version 6.0
QM001 Quality Policy at issue 10, dated 02.09.2020
QM 01.2 Continuous Improvement and Food Safety and Culture Plan at issue 1, dated 25.05.2021
QM005.1 Legislation Register at issue 1, dated 02.09.2020
QM031 Allergen Policy at issue 5, dated 07.01.2020 and RA001 Allergen Risk Assessment at issue 2, dated 22.08.2020
HARM RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020
VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020
D14.4 Supplier Vulnerability Assessment at issue 2, dated 03.01.2018
Site statement of Compliance BOPP Films issue date 02.09.2020, valid until 01.09.2023, no recycled materials, confirming compliance to all current relevant legislation as example 2023/2006, EU10/2011 and 2020/1245
Raw Material Supplier Polivouga Declaration of Compliance dated 14.08.2020 confirming compliance to documented relevant legislation and Amplas migration test report ref 18/0115 with results well within the migration limits laid down in the EU10/2011 directive
Site Product Technical Data Sheet RXD PVdC coating BOPP core layer Enhanced low seal PVdC coating defining functionality and typical values such as OTR using test method ASTM 1927, WVTR using test method ASTM 1249 and Static COF using test method ASTM 1895 dated 17.10.2020
SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021

1.2	Management review

There is an annual Management Review Meeting undertaken at the site held under SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, conducted on the 24.09.2020 and attended by the M.D., Operations Director, Operations Manager, Quality Manager, QA Assistant and Technical Engineer.
The management agenda covers all the elements required in the standard including policy, environmental , training, product withdrawal/recalls, KPI's action plans and timeframes , results of internal, second-party and third-party audits including the effectiveness of root cause and corrective actions, out of specification products, customer performance indicators, complaints, review of HARM system, supplier performance, resource requirements, legislation, the effectiveness of the product defence and product fraud prevention plans and the site's performance against the standard and objectives. Minutes are circulated to all attendees with action points allocated to designated personnel with a timescale for completion. The outputs from the review are communicated through supervisory channels and monthly management meetings which review targets and objectives taking any necessary action. All employees have contact with the Senior site Team and issues regarding safety, quality and legality are easily raised through supervisory Channels. Minutes viewed were compliant with the requirements of the standard, adequately discussed and effectively reviewed. Employees are made aware of their responsibilities through effective comprehensive training programmes and work instructions evidenced during the site tour, discussions with staff and by review of training records.
Audit Evidence;
SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020

1.3	Organisational structure, responsibilities, and management authority

There is a documented Organogram in place SOP 16.1 Organogram. Key personnel are displayed along with clearly defined reporting channels and the chart displayed as a tiered structure starting at the CEO and M.D. and ending at the Production Operatives. SOP 16.2 Deputies and SOP16.3 Job Roles clearly define roles, responsibilities, reporting channels and identifying personnel responsible for product safety, legality, regulatory compliance, quality and the deputies. All key staff are aware of their responsibilities within the site and roles and resources reviewed annually at the management review. The Quality Manager is the dedicated BRCGS Management Representative and QA Assistant as the deputy. Job descriptions are in place and issued to all personnel upon commencement of employment. All key staff are made aware of their responsibilities within the site via a site induction and job specific on-the-job training with refresher training as required. SOP'S/Work instructions are issued for each job. Reviewed quality manager, operations director and operations manager job descriptions which clearly defines responsibility for quality safety and legality issues for the site. Employees have access to work instructions with work carried out in accordance with instructions observed during the site tour, through staff interviews and review of training and competency records.
Audit Evidence;
Site Tours on 01st and 02nd July 2021
SOP 16 Organogram, SOP 16.2 Deputies and SOP16.3 at issue 10 dated 07.06.2021

Non-applicable clauses	None

2.	Hazard and risk management
2.1	Hazard and risk management team

Covered under HARM Plan at issue 2, dated 29.03.2021. The multi-disciplinary team in place includes QA assistant (team leader), Technical Engineer, Operations Manager, Machine Operator, QA Assistant and Warehouse Operator. All team members have been formally trained in HACCP principles, certificates are in place at the site and the team have extensive experience in the packaging industry with all the necessary skills to ensure the HARM system is fully implemented and its effectiveness evaluated. The team are kept updated by any changes in the factory and customer requirements through being actively involved in the business on a day to day basis. There is no external expertise used for the maintenance of the HARM System.
Audit Evidence;
HARM Plan at issue 2, dated 29.03.2021
Team Leader High Speed Training Level 3 HACCP, dated 03.02.2020 and Warehouse 0perator Advanced food safety Level 2 HACCP dated 02.11.2018

2.2	Hazard analysis and risk assessment

The site has carried out a hazard and risk analysis in accordance with the requirements of this standard, section 2 using the 7 principles of HACCP under HARM Plan at issue 2, dated 29.03.2021. No FMEA or other techniques are used.
The study includes all products and processes from receipt of raw materials, outwork, production stages, despatch of finished goods and customer returns and is supported by Process Flow Charts and Hazard Analysis. The HARM team have maintained an awareness of historical and known hazards including raw materials, intended use of the product, likely product defects that affect safety or quality, relevant codes of practice and legislative guidelines. The plan considers potential for malicious intervention, food fraud, allergens, potential for unintended migration of substances, hazards that may have an impact on the functional integrity and performance of the final product, defects critical to consumer safety, legality, loss of essential information, microbial, physical and chemical hazards. The scope of the study is outsourced centre folding, of gravure, digital and flexographic printing, lamination and die-cutting and the

slitting, rewinding, hot needle perforation, core cutting, of polypropylene, polyethylene, amorphous polyethylene, terephthalate, polyamide, ionmer (Surlyn), metallised APET, OPA, EVOH, OPP, LLDPE, PVdC to produce films on the reel, pouches and lids for food products. No in-line testing is deemed necessary. There are TACCP and VACCP studies documented to support the study. Full product descriptions and raw material composition is documented. The technical specification defines the composition of the substrate, artwork, functionality test methods and packing instructions. Specifications written are agreed by the customer and held on the site MIS. No post recycled material used. The process flow chart has been verified during the last full HARM review undertaken on the 29.03.2021 and defines the operations on site including;

- Receipt and approval of artwork
- Purchasing
- Goods in
- Slitting/perforation
- Printing/lamination/Die cutting/Centre folding (Outsourced)
- Finished goods storage
- Despatch
- Customer returns
- Rework

The study is inclusive of risk assessments using a traditional 5x5 HACCP matrix methodology and given all hazards a risk rating. The likelihood and severity scores are assigned and used to calculate the risk rating, with high-risk categories >20 put through the decision tree to define if it should be classed as a CCP. The team have assessed the risk levels of all identified hazards associated with the production of the packaging and classified no hazards as CCP's. The site keeps abreast of standards, legislative changes, industry codes of practices and technical and scientific developments though the Packaging News, Plastics Weekly, suppliers, customers, BRCGS and food.gov.uk. The non-conforming product procedure is initiated in the event of a failure and includes quarantining the affected material carrying out a full investigation including root cause and preventative action. The corrective action taken when monitored results indicate a failure to meet the control limit is established and documented in Works Instructions and QC procedures including quarantining and evaluating potentially out-of-specification products to ensure they are not released until their safety, quality and legality can be established. All identified hazards are controlled via the existing WI's, SOP's, GMP and the established PRP's. Control measures include, supplier approval, process control and start up procedures as examples. Hazards managed by pre-requisite programs include personnel hygiene, cleaning, maintenance, glass and brittle materials and pest control as examples. The effectiveness PRP's are reviewed to ensure they adequately control the risks identified and, where necessary, improvements implemented through internal audits. The Hazard analysis is reviewed and validated at management review meetings, at the annual HARM meetings and through internal audits. Last annual HARM and flow chart team verification review and minutes dated 29.03.2021 viewed and included actions, responsibility, timescale and closure. The team are reconvened to re-evaluate the risk analysis study If or when a product withdrawal/recall occurs. Verification of the system is undertaken following serious complaints, process changes, product failures, recalls, product withdrawals, any serious failures on internal audits of pre-requisite programmes and external third-party audit. There have been no product recalls or withdrawals since the last evaluation and no hygiene or foreign body complaints within the last 12 months.

Audit Evidence;

HARM Plan at issue 2, dated 29.03.2021
HARM RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020
VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020
D14.4 Supplier Vulnerability Assessment at issue 2, dated 03.01.2018
Site statement of Compliance BOPP Films issue date 02.09.2020, valid until 01.09.2023, no recycled materials, confirming compliance to all current relevant legislation as example 2023/2006, EU10/2011 and 2020/1245
Raw Material Supplier Polivouga Declaration of Compliance dated 14.08.2020 confirming compliance to documented

	relevant legislation and Amplas migration test report ref 18/0115 with results well within the migration limits laid down in the EU10/2011 directive Site Product Technical Data Sheet RXD PVdC coating BOPP core layer Enhanced low seal PVdC coating defining functionality and typical values such as OTR using test method ASTM 1927, WVTR using test method ASTM 1249 and Static COF using test method ASTM 1895 dated 17.10.2020 SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020 QM005.1 Legislation Register at issue 1, dated 02.09.2020 QM031 Allergen Policy at issue 5, dated 07.01.2020 and RA001 Allergen Risk Assessment at issue 2, dated 22.08.2020 SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021 SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020
Non-applicable clauses	2.2.9/10/11 No CCP's

3.	Product safety and quality management
3.1	Product safety and quality management system

There is a fully implemented, accessible easy navigable product safety & quality manual at issue 3, dated 02.09.2020 in place with an index of associated processes and procedures in QM contents. The manual is approved by the MD and the system has been specifically designed to meet BRCGS and ISO 9001 requirements. Policies & Procedures are approved by the relevant manager. The QMS at the site is a mixture of hard copy and electronic with electronic documents stored securely on password protected PC's which are backed up daily. The QMS is accessible to all key personnel on site and electronic documents are available as read only. Individual Policies, Risk assessments, Hygiene Procedures, SOP's and work instructions are in place that support the system. The effectiveness of the system is reviewed during the Management Review Meetings and opportunities for improvement are implemented as necessary. The system is also reviewed when any changes to the site's processes or procedures occur, including changes to the standard and is subject to internal audits. The system is available in English only

Audit Evidence;

QMS at issue 3, dated 02.09.2020

3.2	Document control

Covered in SOP18.1 Control of Documents Procedure at issue 7, dated 02.07.2017, all changes to documents and records and the recall and replacement of obsolete documents are recorded on the SOP18.2 Document Log /Obsolete Documents at issue 2, dated 14.01.2017. Document control protocol is title, reference number, issue number, date and owner and complies with the requirements of the standard. Documents are controlled by document master lists and change control protocols. along with the reason for the change. Site documentation is controlled and amended when applicable by the Quality Manager or Deputy and approved by departmental heads apart from Policies that are approved by the M.D. or Operations Director before re-issue. Manufacturing instructions are distributed in the job pack that follows the job through all stages of the process. Documentation reviewed during the assessment was observed to be correctly authorised, matched the document register and using the correct version. Electronic documents are protected on password protected systems which incorporate anti-virus controls and are backed up daily. The system is available in English only back up of electronic systems.

Audit Evidence;

SOP18.1 Control of Documents Procedure at issue 7, dated 02.07.2017
SOP18.2 Document Log /Obsolete Documents at issue 2, dated 14.01.2017
Last change recorded was for a change to SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021, approved correctly and delisted on 08.04.2021
Site Tours on 01st and 02nd July 2021

3.3	Record keeping

Covered under SOP15 Quality Records Procedure at issue 5 dated 01.04.2021 dated 27.11.2017. Records pertaining to product safety, legality, and integrity were readily available demonstrated at the vertical audit, hard copy records were in good condition, legible, maintained and up to date. All documents seen were appropriately approved in line with procedures and any alterations would be justified and approved. Changes to records are dealt with in the same way as changes to documents with the reason for change recorded and signed off. The system is both computer and hard copy based with operators at each workstation capturing production and quality data. The retention time for hard copy records is defined as 3 years, electronic records are held indefinitely and is over the defined shelf life of the product defined in specifications and statements of compliance as 12 months. Electronic records are stored securely on password protected systems with anti-virus controls and backed up daily as 3.2. Records viewed and completed correctly on correct forms referenced in this report included as examples;

- Cleaning records
- Pest control records
- Internal audit records
- Supplier records
- Customer complaints records
- Traceability tests/ Product withdrawal test records

Audit Evidence;
Site Tours on 01st and 02nd July 2021
SOP15 Quality Records Procedure at issue 5 dated 01.04.2021 dated 27.11.2017
Site statement of Compliance BOPP Films issue date 02.09.2020, valid until 01.09.2023, no recycled materials, confirming compliance to all current relevant legislation as example 2023/2006, EU10/2011 and 2020/1245 defining shelf life as 12 months
Site Product Technical Data Sheet RXD PVdC coating BOPP core layer Enhanced low seal PVdC coating defining functionality and typical values such as OTR using test method ASTM 1927, WVTR using test method ASTM 1249 and Static COF using test method ASTM 1895 dated 17.10.2020 Shelf life 12 months
3.3.4 Product Lifetime Retention Record RA-BRC6-001 dated 09.05.2021

3.4	Specifications

Covered in QM03 Specifications Policy at issue 5, dated 28.06.2021 and HARM. Site suppliers of raw materials supply relevant declarations of compliance, certificates of analysis, inspection certificates and material safety data sheets, which includes any legislation and migration testing compliance where applicable. Specifications were challenged and found to exist for all products manufactured at the site and all raw materials held on the MIS and generated in conjunction with customer services, sales, quality, production and the customers. Specifications are suitably detailed and includes composition, legal compliance, functionality claims and test methods for verification and application. The site technical specifications references the customer unique reference number, material, dimensions and test methods and is used for generating work orders. All products manufactured on site conform to current legislation and legislative compliance are detailed on the site SOC and supplier DOC's. Specifications are formally agreed between the customer and the site after the design or specification generation process has been completed. Specifications include functional

claims and reference intended use of packaging, functional properties, include reference to the standard test methods used and limits/tolerances and are agreed with the customer as part of the acceptance procedures. Quotations and/or order acknowledgements are sent to customers for orders prior to any production run taking place. Site SOC is fully compliant with the standard and include the materials used in the composition of product, legislative requirements/compliance, inclusion of recycled materials, issue and defines intended use and limitations of use. Customer trademarks are used and agreed formally between all parties at the design stage, prior to any production runs as and when applicable. The order processing procedure includes conducting a specification review on each order by the customer service teams. All changes or amendments to existing specifications are approved by QA/Sales and the Technical Engineer for consideration and possible implications. All material specifications are held on the database and reviewed annually or in the event of any changes. Once a change has been authorised the relevant specification is updated and stored on the database and the new specification issued and declaration of compliance is reviewed. Any changes to agreements or contracts are agreed, documented and communicated to appropriate departments across the site. Only authorised people have access to the specifications and servers are routinely backed up to prevent any loss or damage to files. Occasionally manufacturing logos or trademarks are added to the product and agreed through the design stages.

Audit Evidence;

QM03 Specifications Policy at issue 5, dated 28.06.2021
3.4.3 Statement of Compliance Review Frequency RA-BRC6-002 dated 10.05.2021
3.4.5 Specifications Review Frequency RA-BRC6-003 dated 12.05.2021
Site statement of Compliance BOPP Films issue date 02.09.2020, valid until 01.09.2023, no recycled materials, confirming compliance to all current relevant legislation as example 2023/2006, EU10/2011 and 2020/1245
Site Product Technical Data Sheet RXD PVdC coating BOPP core layer Enhanced low seal PVdC coating defining functionality and typical values such as OTR using test method ASTM 1927, WVTR using test method ASTM 1249 and Static COF using test method ASTM 1895 dated 17.10.2020
Site Tours on 01st and 02nd July 2021 reviewing specifications generated in use and vertical audit
Raw Material Supplier Polivouga Declaration of Compliance dated 14.08.2020 confirming compliance to documented relevant legislation and Amplas migration test report ref 18/0115 with results well within the migration limits laid down in the EU10/2011 directive
Cert of Conformity Staveley Packaging food grade bag supplier dated 22.05.2019
TLS BOPP Food Contact Declaration dated 22.05.2019 and Taghleef Declaration of Compliance dated 01.04.2020

3.5	Internal audits

Covered under QM023 Internal Audit Policy at issue 8, dated 28.06.2021, SOP23.0/1/2/3 area GMP Inspections at issue 1, dated 29.10.2020, SOP012.1 Internal Audit Schedule, 3.5.1 Internal Audits Frequency RA-BRC6-004 dated 06.05.2021, 3.5.5 GMP Audits Frequency RA-BRC6-005 dated 04.05.2021 and SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021. The 2021 internal audit schedule viewed has a defined scope and considers all activity of the HARM and product safety plan in place and includes PRP's HARM and all of the sections of the standard including food fraud and defence. The 2020 schedule was completed and the 2021 schedule is on plan and is fully implemented and effective evidenced in the compliance audit. Audits are undertaken in relation to the risks associated with the activity, previous audit performance, occur at least annually and are spread throughout the year. Corrective Action Report with root cause analysis is completed as part of the investigation. N/C's are required to be completed within a defined time period bases on the seriousness of the issue. Department leaders are allocated tasks for rectification of any issues raised and root cause and preventative action reviewed by the auditors and quality manager before sign off to ensure satisfactory closure. All internal audits are done by three trained auditors to ensure impartiality. The findings are reviewed at the management review meetings. The audits record compliance as well as non-compliance. Any unsatisfactory audit may result in a re -audit of area or process dependant on findings. In addition, GMP audits are carried out monthly and reviewed daily as part of

site production meeting based on risk to ensure pre-requisite programmes are effective.
Audit Evidence;
SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020
QM023 Internal Audit Policy at issue 8, dated 28.06.2021, SOP23.0/1/2/3 area GMP Inspections at issue 1, dated 29.10.2020, SOP012.1 Internal Audit Schedule, 3.5.1 Internal Audits Frequency RA-BRC6-004 dated 06.05.2021, 3.5.5 GMP Audits Frequency RA-BRC6-005 dated 04.06.2021 and SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021
SM lead auditor training by Benchmark Business Training dated 22.01.2016 and TL auditor training by High Speed Training dated 29.04.2021
Reviewed internal audit reports for SOP14 approved suppliers dated 08.01.2021, Pest Control dated 12.01.2021, HARM dated 14.01.2021, SOP001 Design and Development dated 10.03.2021 and site standards dated 22.04.2021 comprehensively documenting evidence of conformity and no N/C's raised
Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed

3.6	Corrective and preventive action

The site has procedures in place for Corrective and Preventative Action under HARM and SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021.
The procedures identify defects that may initiate the procedure and include as examples physical, chemical, microbiological contamination and tampering. The procedure is followed as part of internal audits, internal non-conformance, customer complaints and supplier issues and includes root cause and preventative action. The effectiveness of corrective and preventative action is reviewed at management meetings evidenced in minutes of the site annual management review including trend analysis, review of complaints and non-conformances.
Audit Evidence;
SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021
SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020
Previous BRCGS Audit Report dated 10.01.2020
Complaints have reduced significantly from 32 to 15 comparing 2020/2021 demonstrating the effectiveness of root cause and preventative action
Reviewed as part of complaints assessments including NC Report dated 09.04.2021 for film joint not metallised and root cause, corrective and preventative action included caused by technician omitting requirement and all specifications reviewed and additional checks implemented and closed on 13.04.2021 and NC Report dated 19.04.2021 for issues with product running effectively on customers machine and was followed by a site visit to the customer by the Technical Engineer and the machine manufacturer to resolve the customers training and machine issues dated 21.05.2021

3.7	Supplier approval and performance monitoring

Covered under QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021, SOP14 Supplier Approval and Performance Procedure, SOP14.1 Supplier Questionnaire, SOP14.2 Supplier Assessment at issues 4, dated 13.08.2020, SOP14.3 Approved Supplier List, 3.7 Supplier Approval/ Monitoring RA-BRC6-006 dated 09.05.2021 HARM, Food Defence Plan, VACCP and TACCP. All new suppliers are subject to a site inspection by a Company Director/Quality Manager and complete the Packaging Assessment Supplier Questionnaire which requests information regarding the company's Management Information System, any certifications the company hold & information pertaining to the company's performance history to supply relevant goods or services. Certification to a recognised Quality Standard is a pre-requisite to supply Food Contact materials. Suppliers are subject to a probationary period and once fully approved added to the Approved Suppliers List are then subject to continual on-going performance review procedures by Purchasing and Technical personnel. The approved supplier list records if supplier DOC's are on file, specifications are on file, expiry dates of certificates and dates suppliers' questionnaires received back from suppliers. Only approved suppliers are used. In the event of an exception trial orders, COA's or DOC's would be requested prior to using any material. Established supplier questionnaires are reviewed by an experience and competent auditor and include HARA, product safety, traceability and good manufacturing practices. Suppliers' traceability systems are tested on first approval and every 3 years. All suppliers are requested to inform the site of any changes including site's certification status. The last manufacturer of Agents / Brokers or Wholesalers is known. On-going Supplier Performance Review is based on risk and performance criteria and supplier approval records are in place for suppliers of all raw and packaging materials. Most materials are sourced from internationally recognised companies. All materials viewed on site tours were appropriately approved and on the supplier list.

Audit Evidence:

HARM RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020
VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020
D14.4 Supplier Vulnerability Assessment at issue 2, dated 03.01.2018
QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021, SOP14 Supplier Approval and Performance Procedure, SOP14.1 Supplier Questionnaire, SOP14.2 Supplier Assessment at issues 4, dated 13.08.2020, SOP14.3 Approved Supplier List, 3.7 Supplier Approval/ Monitoring RA-BRC6-006 dated 09.05.2021
Viewed raw material suppliers Alupol Films BRCGS certificate, Flexi P Film BRCGS certificate and supplier questionnaire dated 19.08.2020, Casfil BRCGS certificate and raw material suppliers and outsourcers Polivouga BRCGS certificate expiry 19.07.2021, SOP14.2 Supplier and Out Sourced Process Assessment dated 23.01.2021, SOP14.1 Supplier Assessment Questionnaire dated 23.01.2021, BPK Packaging BRCGS certificate expiry 02.12.2021, Hatzopoulos BRCGS Certificate expiry 26.06.2022 and TCL BRCGS certificate expiry 23.02.2022, SOP14.2 Supplier and Out Sourced Process Assessment dated 09.02.2021 and SOP14.1 Supplier Assessment Questionnaire dated 09.02.2021
Site Tours on 01st and 02nd July 2021 reviewing suppliers on the SOP14.3 Approved Supplier List, SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020

3.8	Product authenticity, claims and chain of custody

Product authenticity and chain of custody is covered under HARM, RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020, VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020, D14.4 Supplier Vulnerability Assessment at issue 2, dated 03.01.2018, QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021 and SOP14 Supplier Approval and Performance Procedure. The site has processes in place to access information on historical and developing threats to the supply chain which may present a risk of substitution of raw materials using, BRCGS, suppliers, customers and trade press. The documented vulnerability assessment has been carried out on all raw materials to assess the potential risk of substitution. No materials identified as at risk based on historical evidence, economic factors, ease of access to supply chain, nature of the raw material and no testing deemed necessary. The output from this assessment is the documented vulnerability assessment plan. This plan is kept under review to reflect changing economic circumstances and market intelligence which may alter the

potential risks and is formally reviewed annually.
Audit Evidence;
HARM, RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020, VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020, D14.4 Supplier Vulnerability Assessment at issue 2, dated 03.01.2018, QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021 and SOP14 Supplier Approval and Performance Procedure
SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020

3.9	Management of subcontracted activities and outsourced processes

Covered under QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021, SOP14 Supplier Approval and Performance Procedure, SOP14.1 Supplier Questionnaire, SOP14.2 Supplier Assessment at issues 4, dated 13.08.2020, SOP14.3 Approved Supplier List, 3.9.2 Outsourced/ Sub Contracted RA-BRC6-008 dated 09.04.2021 HARM, Food Defence Plan, VACCP and TACCP. Outworkers are employed to print, laminate, die cut and centre fold films to the site's specifications, as well as supplying plain and printed pouches. They are all approved and BRCGS certificated. Customers are made aware of outworker operations at design and contract review.
The sites QC procedures ensure the final release of the product remains the responsibility of the site for work requiring further processing to ensure the quality and safety meets the specification prior to despatch. Clear specifications are agreed for all work outsourced. Performance is reviewed at management meetings
Audit Evidence;
QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021, SOP14 Supplier Approval and Performance Procedure, SOP14.1 Supplier Questionnaire, SOP14.2 Supplier Assessment at issues 4, dated 13.08.2020, SOP14.3 Approved Supplier List, 3.9.2 Outsourced/ Sub Contracted RA-BRC6-008 dated 09.04.2021
HARM, RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020, VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020, D14.4 Supplier Vulnerability Assessment at issue 2, dated 03.01.2018
Outsourcers Polivouga BRCGS certificate expiry 19.07.2021, SOP14.2 Supplier and Out Sourced Process Assessment dated 23.01.2021, SOP14.1 Supplier Assessment Questionnaire dated 23.01.2021, BPK Packaging BRCGS certificate expiry 02.12.2021, Hatzopoulos BRCGS Certificate expiry 26.06.2022 and TCL BRCGS certificate expiry 23.02.2022, SOP14.2 Supplier and Out Sourced Process Assessment dated 09.02.2021 and SOP14.1 Supplier Assessment Questionnaire dated 09.02.2021
Reviewed customer notification of use of outworker on specification agreed, specification sent to outworker, goods in QC checks for work returned and goods out checks to sites customer completed for Customer order and order acknowledgment dated 03.03.2021 for specification PP-COO324-01 V1, purchase order 1563, raw material and specification sent to TLC on 10.03.2021 BOL 1563, Goods in checks DN470929 on 29.03.2021 and goods out checks for delivery to customer DN2035 on 02.04.2021

3.10	Management of suppliers of services

Covered under QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021, SOP14 Supplier Approval and Performance Procedure, SOP14.1 Supplier Questionnaire, SOP14.2 Supplier Assessment at issues 4, dated 13.08.2020, SOP14.3 Approved Supplier List, 3.10 Approval and Monitoring of Service Suppliers RA-BRC6-009 dated 10.05.2021, HARM, Food Defence Plan, VACCP and TACCP.
The site service providers have been assessed based on the risk to product safety, legality and quality and any specific legal requirements. All suppliers are approved and monitored through individual procedures with an Approved Supplier list in place containing Pest Control, Transport, Waste, Laundry and Calibration as examples. Agreements are documented as purchase orders or contracts. Approval is carried out annually based on verification of certification and

any risks identified in the vulnerability and product defence plan. Water, electricity or gas are excluded on the basis of risk.

Audit Evidence:

QM027 Supplier Approval and Monitoring Policy at issue 6, dated 01.04.2021, SOP14 Supplier Approval and Performance Procedure, SOP14.1 Supplier Questionnaire, SOP14.2 Supplier Assessment at issues 4, dated 13.08.2020, SOP14.3 Approved Supplier List, 3.10 Approval and Monitoring of Service Suppliers RA-BRC6-009 dated 10.05.2021
Biffa waste Service CBDU 104360 expiry 23.05.2022
HARM, RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020, VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020
Premier Pest Control BPCA M15/ 683 expiry 28.02.2022 and 2021 contract
ADD Express supplier assessment questionnaire dated 05.11.2019 and the Pink Link haulier signed agreement for distributing food contact packaging securely and hygienically dated 05.09.2019 and ADD Express agreement documenting requirements for transporting food packaging dated 16.09.2019
Blackburn Waste CBDU 87670 expiry 14.02.2022
Ellis Laundry site audit supplier questionnaire dated 22.10.2019

3.11	Traceability

Covered under QM41 Traceability Policy at issue 2, dated 28.05.2021. The site has traceability procedures in place to identify its products through all stages of the manufacturing processes undertaken at the site, from the intake of Raw Materials to the dispatch of Finished Goods and vice versa. No rework carried out. Reels of plain, or printed film and outworked WIP/ Products are delivered by suppliers and are identified by Batch Numbers, Reel I.D. Nos. Supplier Name and Country of Origin. All raw material reels are recorded on an electronically generated GRN system, allocated a batch number and bar coded and is the basis of traceability throughout the production process. Pouches and lids are boxed and labelled with batch numbers, supplier name and country of origin and a bar code attached after receipt. Operators attach bar code labels to every reel or box before wrapping and despatching. The Customer can identify the product from the bar code, box or reel label, pallet label and the delivery note. This information can be traced back to the original material used in the production of the product. Any product found to be defective would be identified and segregated from similar conforming product. Effective identification of raw materials, intermediate products, finished products, non-conforming products and quarantined goods was observed during the site assessment to ensure traceability. Outsourcing traceability is maintained. Coding is checked and traceability of test data and samples to production lots is maintained. The system is tested at least annually by the site. Records for the site trace test were timed and the trace test challenged at audit records were readily available, highly detailed and retrieved within a few hours**.**

Audit Evidence:

Site raw material to finished goods trace test carried out on 07.01.2021 supplier UAB Lietpak BRCGS certified site code 1694482, PO to Lietpak dated 30.10.2020 material 150PA135PEBL610G delivered on delivery note 80062810 on 27.11.2020, pallet ref 2867556 stock locations AO7/302/24 used on customer order PO210107005 and finished goods to raw material trace test carried out on 07.01.2021 work order 61938, despatched to customer on 17.12.2020 and raw material traced to Tagleef PO14505 delivered on 22.09.2020 reels numbers 278136/6/7/8/9. Full traceability demonstrated
Trace challenged at audit for new product artwork ref 210329 approved on 15.03.2021, customer order and order acknowledgment viewed , specification PP-COO324-01 V1 generated, checked and approved using SOPD2-4 Print Order Check Sheet, Raw material from purchase order 1563 delivered on delivery note 14564 dated 15.12.2020 reel ID 2877665, slit on work order 201288 on 09.03.2021, slit material and specification sent to TLC on 10.03.2021 BOL 1563, printed product goods in checks carried out on delivery note number DN470929 on 29.03.2021 and goods out checks for delivery to customer DN2035 on 02.04.2021 and competed SOPD2-4 Print Order Check Sheet. All approvals,

specifications QC goods in and out checks, first off samples and running QC tests completed and line clearance recorded with full traceability demonstrated

3.12	Complaint handling

Covered under SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021. Complaints are fully investigated by the Quality Manager and Relevant Managers and closed out by the Quality Manager. The investigation findings are documented together with any steps taken to prevent reoccurrence of the problem. Complaints are recorded with details of date and fault. The root cause of the complaint is documented and preventative action taken. The effectiveness of corrective and preventative action is reviewed at management meetings evidenced in minutes of the site annual management review including trend analysis, review of complaints and non-conformances.

Audit Evidence;

SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021

SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020

Previous BRCGS Audit Report dated 10.01.2020

Complaints have reduced significantly from 32 to 15 comparing 2020/2021 demonstrating the effectiveness of root cause and preventative action

Reviewed NC Report dated 09.04.2021 for film joint not metallised and root cause, corrective and preventative action included caused by technician omitting requirement and all specifications reviewed and additional checks implemented and closed on 13.04.2021 and NC Report dated 19.04.2021 for issues with product running effectively on customers machine and was followed by a site visit to the customer by the Technical Engineer and the machine manufacturer to resolve the customers training and machine issues dated 21.05.2021

3.13	Management of product withdrawals, and incidents and product recalls

The management of product withdrawal is under SOP19 Product Withdrawal and Recall procedure at issue dated 15.10. 2020.Written guidance of what would constitute an incident is documented in the procedure and staff are trained in the procedure in induction and refresher training. Examples of incidents are listed in the procedure e.g., glass, sharps and chemical. Incidents are recorded. The withdrawal procedure can be operated at any time. Investigations pending a decision to withdraw a product incorporate root cause analysis and subsequent corrective action & preventative action is taken following an incident. Sales have contact lists for customer and they have out of hours details of site staff. Any incident is recorded on an Incident Report and acted upon immediately There is a Product Withdrawal/Recall team in place including MD, Quality Manager, Assistant Quality Systems, Production and Technical Staff with contact numbers provided. Investigations include root cause analysis and are undertaken by the team. All affected stock is quarantined, scope of problem determined, quantities affected and actions assigned to Withdrawal/Recall Team Members with Customer Services / Sales and Key staff advised and briefed. Customers are notified of need to quarantine stock and certification body advised. Transport arranged for uplift of stock and disposal. The test records key timings at each key stage. Effectiveness of withdrawal against plan is assessed and recommendation of changes to plan completed. A procedure to manage product recalls is included and identifies the key personnel involved in recalls, together with clearly defined responsibilities, a communications plan to inform customers and regulatory bodies in a timely manner. The product withdrawal procedure is tested annually, in a way that ensures its effective operation and any withdrawals or recalls are reviewed to identify and implement appropriate improvements.

Audit Evidence:

Site test completed on 24.11.2020 for product delivered ref 2011260007 on 19.11.2020 and included a full traceability test. The test was timed and reviewed	
Non-applicable clauses	3.8.3 no materials at risk

4.	Site Standards
4.1	External standards

Covered under QMOO8 External Standards Policy at issue 3, dated 02.09.2020, 4.1.1 Local Activities RA-BRC6-0012 dated 09.06.2021 and 4.1.3 Building Fabric RA-BRC6-0013 dated 15.05. 2021.All external areas of the building were viewed during the assessment. The site dates from the early 2000's and is located on an industrial estate in Birkenshaw on the outskirts of Bradford. No neighbours pose any product risk. Doors and windows were closed. The site perimeters are fenced, with electric gates. The building is proofed against pest ingress with doors locked. The building fabric is well not maintained with no gaps in the structure observed. No issues identified by the pest contractor. Externally there are large areas for loading/ unloading and storage of waste skips. No evidence of release of waste unto the environment. External standards of the sites are in good condition. Drains are covered and effective. CCTV covers external areas of the sites and there is good external lighting. The building construction is steel integral frame with external steel cladding, with a steel corrugated sheeted roof incorporating sky lights and is well maintained. External traffic routes are surfaced with concrete maintained to an acceptable standard, with landscaped areas well maintained. Vehicles are loaded externally. There is a clear unobstructed view around the external walls with appropriate pest proofing and external areas protected with bait points. Utilities pipework going into and out of the factory are suitably sealed. General refuse materials are decanted from bins into designated skips stored outside, were not overflowing and no concerns raised by the pest control contractor. The pest contractor is approved via the supplier approval procedure and is a British Pest Control Association registered contractor. Fabric inspections are carried out as part of GMP audits.

Audit Evidence:

Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed
Site Tours on 01st and 02nd July 2021

4.2	Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas

Covered under QM008 Building Fabric and Product Flow Policy at issue 3, dated 02.09.2020, 4.2.4 Glass Windows and 4.2.5 Glass Register RA-BRC6-0014 dated 09.04.2021 and 4.2.8 Ventilation RA- BRC6-0015 dated 24.05.2021. All internal areas were viewed during the assessment including storage, welfare facilities, waste storage, warehouse, production and offices. Internal areas and building fabric are maintained in a good condition. No potential contamination issues were observed Fabric construction is steel integral frame with external steel cladding, steel cladded roofs, internal sealed painted concrete floors with some painted block walls and facilitates cleaning. There are painted designated walkways in production and storage areas that are well maintained with no flaking or chipped paint in evidence
Ventilation is of natural Provision. No windows pose any risk. Ceilings are steel cladding with polycarbonate skylights. No suspended ceilings, internal drains or overhead walkways. Walls, floors, ceilings and ledges were viewed and were clean and hygienic and posed no risk to products. Offices are located away from production and have their own entrance. Lighting in production and storage areas, including EFK units are suitable and is subject to shatterproof and/or protected tubing. All areas of the factory are provided with good levels of illumination. No evidence of breakages evident on-site tour. External doors are proofed against pest ingress. Minimal wooden equipment in use

and any viewed was sealed and not splintering. The building is suited to the production of food contact packaging materials and is audited as part of hygiene audits.
Audit Evidence:
Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed
Site Tours on 01st and 02nd July 2021

4.3	Utilities

Covered in HARM. Water is used predominantly at the site for cleaning purposes. It is via mains supplies provided by Yorkshire Water and of potable quality. Compressed air does not come into direct contact with the product, is utilised on machinery for operational control of valves & cylinders and is dried & oil separated. Based on risk assessment compressors are monitored and serviced to a schedule based on hours run and poses no risk to the product. Compressed air is filtered to 0.01 micron and filters changed in line with manufacturers recommendations and food grade lubricants used. Competent service provider is employed to service the compressed air systems on the machines. Food grade oils are listed on the approved chemical list.
Audit Evidence:
Site Tours on 01st and 02nd July 2021
NC Air compressor Service records dated 15.10.2020 ref 20205

4.4	Site security and product defence

Security was assessed through auditor signing in procedures, the site tours and document reviews. The site has a documented procedure and risk assessment for security that describes the control measures in place. The threat assessment includes both internal and external threats. Only authorised access allowed to production and storage areas. Signage is clearly displayed on reception and non-authorised. The sites are protected with electronic gates and a call entry reception system for visitors and contractors. Drivers must call to gain entry / exit and not allowed into factory. The building is alarmed, and the alarm is set when the business is unoccupied. Security lighting is in place and a CCTV system There are designated entrances to the buildings which were locked with fob-controlled access for employees. These plans are kept under review to reflect changing circumstances which may alter the potential risks and reviewed annually. The need to report any unidentified / unknown visitors is trained out to all staff during induction evidenced in training records and includes security awareness training. Threat awareness includes IT security and internal and external issues. All visitors must sign in and complete a health questionnaire before entering the site. Agency and new employees' references supplied are followed up with background checks in operation All visitors and contractors are supervised whilst on site. Backing up of computer systems in place with security procedure as 3.2
Audit Evidence:
Site Tours on 01st and 02nd July 2021
HARM Plan at issue 2, dated 29.03.2021
HARM RA001 Site Security/ Malicious Intervention risk assessment at issue 4, dated 16.06.2020
VACCP/ TACCP Risk Assessments and Product Defence Plan at issue 2, dated 08.09.2020
D14.4 Supplier Vulnerability Assessment at issue 2, dated 03.01.2018

4.5	Layout, product flow and segregation

Covered under HARM process Flow and QM10.1 Site plan and does not show routes for removal of waster or process flow and was raised as a non-conformance. The plans show people flows and facilities. The production site is designed and maintained to minimise the risk of product contamination or damage and is laid out logically within the constraints of the buildings There is an appropriate laid out linear flow system in production with quality line clearance on changeovers. Segregation in production consists via departmental layout including goods inwards and raw material storage, finished goods storage and despatch, the manufacturing hall and offices. Sorting or other activities involving the direct handling of the product takes place in production areas. The removal of outer packaging is carried out in the warehouse. Separation was in evidence between raw materials, WIP and finished product. The site has adequate space available for all operations with walkways around production equipment. Access points are displayed as part of safety regulations with no access for non-production staff. All Raw Material, finished goods and WIP was observed to be suitably protected in storage and for transfer.

Audit Evidence:

QM10.1 Site plan / HARM Flow 2021

Site Tours on 01st and 02nd July 2021

NC1 Clause 4.5.1 QM10.1 Site plan and does not show routes for removal of waster or process flow

4.6	Equipment

Covered in QM017 Wood Policy at issue 3, dated 12.11.2020, QM025 Equipment and Maintenance Policy and 4.6.2 New Equipment Maintenance RA-BRC6-019 dated 16.04.2021. Equipment is designed specifically for its intended purpose, constructed to facilitate cleaning and maintained to a high standard. Equipment on site consists of Kampf, Titan, Eldec, slitter/rewinders which function as the primary production operation some of which have perforation capability and core cutters. Printing, centre folding, die cutting of lids, pouch production and laminating are outsourced sub-contracted operations. Lubrication points are not able to contaminate the product and food grade lubricants are used if near product. All new equipment is properly specified, tested and commissioned prior to use and cleaning and maintenance routines established following commissioning. All of the production equipment was observed to be maintained in an appropriately clean condition. Minimal wooden equipment in the factory, was appropriately sealed and not splintering. Enclosed noticeboards and laminated notices are used throughout the site and were secure.

Audit Evidence:

Site Tours on 01st and 02nd July 2021

4.7	Maintenance

Covered in QM025 Equipment and Maintenance Policy and 4.7.4 Maintenance Activity RA-BRC6-020 dated 20.04.2021. All equipment and plant are subject to a documented maintenance programme to reduce the risk of breakdown and serviced in line with machine manufacturers specifications. Planned maintenance including basic cleaning and maintenance are carried out by operators and recorded on pads. Maintenance records are recorded by individual machine. Third part engineers carry out servicing and breakdown activities and there is a check of the machine to ensure it is clean and clear to resume production and recorded. The maintenance record system is paper-based and runs to a schedule for each machine. Temporary repairs/modifications using tape, cardboard, etc., are only permitted in emergencies and where product contamination is not at risk. Such modifications are subject to a time limit and are be recorded and scheduled for correction. No temporary repairs observed. No tools were seen out of place during the audit. No engineering workshop. External contractors must sign in at reception and are appropriately supervised and must comply with site hygiene requirements

Audit Evidence:

Site Tours on 01st and 02nd July 2021

Up to date 2021 Cleaning and Maintenance records viewed for all machines in production including Machine K1 work order 202467 with operator DH slitting reel ref 3922, K2 work order 202317-2 with operator TB slitting reel ref 7199, Eldec 3 work order 201711 with operator SH slitting reel ref 320126535, Eldec 3 201603 work order 201603-2 with operator GJ and machine S37 Work order 202544 with operator CA
SOP10.3.1 Maintenance Log and Plan 2021
Viewed third party maintenance records and completed hygiene line clearance signed and countersigned on form SOP010.3.2 at issue 1, dated 28.01.2020 for third party engineering work on 20.05.2021, 06.05.2021 and 18.02.2021 by contractor MJH and on 06.03.2021 by contractor D&H
Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed
Site Tours on 01st and 02nd July 2021

4.8	Housekeeping and cleaning

Covered under HARM, Clean as you go Policy, QM034 Plant Hygiene Policy and Cleaning Procedures at issue 6, dated 30.01.2021, SOP23 GMP Inspection Procedures at issue 1, dated 29.10.2020, 4.8.5 Environmental Monitoring RA-BRC6-022 dated 06.04.2021 and 4.8 Hygiene and Housekeeping Tasks RA-BRC6-021 dated 28.06.2021 detailing, responsibility, methods, cleaning equipment used and verification responsibilities. Cleaning standards are assessed visually, through daily management checks and GMP audits. No environmental swabbing is deemed necessary due to the nature of the substrates and GMP practices in place. Employees have received appropriate training defining their cleaning responsibilities verified by review of training records. The site is very well maintained and good levels of housekeeping and cleanliness observed on floors, walls, ceilings and machines. Documented cleaning schedules are in place for each department with cleaning responsibilities communicated to relevant staff. High level cleaning is carried out every 2 years. Welfare and general factory areas, walkways, toilets, offices etc. is carried out by an third party cleaner with cleaning chemicals stored in secure cleaner's cupboard and equipment segregated by areas. General multipurpose cleaning chemicals are used in accordance with manufacturer's instructions for dilution. Cleaning schedules were observed to be completed for all areas and machines and up to the date of the audit. Cleaning materials are identified, stored securely, are on approved chemicals list, used by trained staff and safety data sheets are available. The sites do not use highly scented cleaning chemicals which could pose a threat to finished product. Cleaning chemicals observed were close capped and used in accordance with manufacturer's instructions. Toilet equipment is stored separately to general cleaning equipment and colour coded.
Audit Evidence:
Up to date 2021 Cleaning and Maintenance records viewed for all machines in production including Machine K1 work order 202467 with operator DH slitting reel ref 3922, K2 work order 202317-2 with operator TB slitting reel ref 7199, Eldec 3 work order 201711 with operator SH slitting reel ref 320126535, Eldec 3 201603 work order 201603-2 with operator GJ and machine S37 Work order 202544 with operator CA
Warehouse Cleaning, Method and Check sheet, Compressor Room, Production and Machines Including High Level Cleaning and Mezzanine floor monthly cleaning records and methods viewed signed, verified and completed March to June 2021
4.8.5 Environmental Monitoring RA-BRC6-022 dated 06.04.2021
Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed
Site Tours on 01st and 02nd July 2021

4.9	Product contamination control
4.9.1	Glass, brittle plastics, ceramics, and similar materials control

Covered in the HARM, SOP17.1 Sharps, Glass, brittle plastics, ceramics, and similar materials control procedure at issue 4, dated 17.02.2019, SOP17.1 Glass, brittle plastics, ceramics, and similar materials register at issue 18, dated 09.07.2020, SOP17.1.1 Glass, brittle plastics, ceramics, and similar monthly audit at issue 13, dated 16.02.2021, 4.2.4 Glass Windows and 4.2.5 Glass Register RA-BRC6-0014 dated 09.04.2021. Glass breakage procedure in SOP021.1 at issue 2, dated 14.11.2017. All glass and brittle plastics that pose a potential product contamination hazard are controlled and recorded onto a glass register for all areas inspected. Items not in the production or storage areas are excluded on the basis of risk. Hygiene incident form is used to report breakages or defects identified during the site GMP inspection or by operators. There have been no breakages reported since the last audit. The register documents all relevant information regarding items, location, number, type and condition. Where damage occurs, a responsible person is in charge of the clean-up operation, ensuring that no other area is contaminated by following the glass breakage procedure. All suspect products are quarantined and disposal of any contaminated product. All incidents are recorded. No unnecessary items of glass or brittle plastics were observed during the factory inspection. No breakages requiring remedial action were noted during the inspection. All light tubing in the production and storage areas were observed to be shatterproof and/or protected and all EFK tubes are shatterproof. No windows pose any risk. Details on cleaning or replacing glass and hard plastic items to minimise the potential for product contamination are included. The site has had no breakage incidents in the last 12 months

Audit Evidence:

Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed
Site Tours on 01st and 02nd July 2021
SOP17.1.1 Glass, brittle plastics, ceramics, and similar monthly audit at issue 13, dated 16.02.2021 and viewed last monthly audit record completed 13.06.2021 with no issues requiring action

4.9.2	Sharps and metal control

Covered in the HARM, QM019 Metal Control Policy at issue 2, dated 04.10.2017, SOP017.2 Knife and Blade Register GMP audits and SOP17.1 Sharps, Glass, brittle plastics, ceramics, and similar materials control procedure at issue 4, dated 17.02.2019. All employees are trained and instructed in the safe handling of sharps and viewed the register that included knifes and blades observed on the site tours. All new sharps are controlled and stored in locked cupboards and only authorised staff have access. Sharps are issued on a one for one basis, with the old blade being disposed of in sealed sharps boxes. Missing blades instigate an incident report. No sharps observed out of place on the machines. Snap off blades are not permitted. Drawing pins, staples, paperclips and other loose fastenings are not permitted in production or warehouse areas and none observed.

Audit Evidence:

Knife and Blades Register correctly identifying knife TB viewed on site tour
Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed
Site Tours on 01st and 02nd July 2021

4.9.3	Chemical and biological control

Covered in the HARM, 4.9.3.2 Biological Control RA- BRC6-0023 dated 07.06.2021, QM031 Allergen Policy at issue 5, dated 07.01.2020, RA001 Allergen Risk Assessment at issue 2, dated 22.08.2020 and 4.8.5 Environmental Monitoring RA-BRC6-022 dated 06.04.2021 used to identify, control and manage any potential risks from microbiological and chemical contamination and any potential allergens. Safety data sheets and risk assessments are also held on file. A list of approved chemicals for purchase is in place, relevant MSDS information is available and can only be used by authorised personnel. Chemicals are kept securely, no strongly scented products observed in use and all chemicals were close capped. Chemical containers were close capped and labelled. Non-production chemicals in use consist of

food grade lubrication oils, oils and greases and cleaning agents stored securely. No hazardous chemicals. The site Environment risk assessment has deemed swabbing is not needed due to the nature of the substrate and GMP practices in place.

Audit Evidence:

Viewed Approved chemical COSHH list and Evans Cyclone Bleach, Rocol FFG spray and Ambersil FG degreaser on site tour and were on approved chemical list with MSDS sheets available

Site Tours on 01st and 02nd July 2021

4.10	Waste and waste disposal

Covered in the HARM, QM015 Waste Disposal Policy at issue 2, dated 04.10.2017 and 4.10 Waste Disposal and Material Flow RA-BRC6-009 dated 10.05.2021 with waste managed on the site in accordance with legislative requirements. Process waste is managed and external drains are protected to prevent release into the environment and none observed. Suitable and sufficient refuse and waste containers are provided, and were viewed to be stored in closed containers, not overflowing and in a clean condition. There is a register in place detailing Waste Contractors in the approved suppliers file correctly identifying the waste companies viewed on the site tour. External storage of refuse showed no issues of pest harbourage or recorded by the pest control contractor. Waste containers are clearly marked across the sites. Plastic process waste is segregated for recycling and secure destruction of printed waste is carried out by an approved and licenced contractor. Printed waste is rarely generated as all printing is outsourced. No

Audit Evidence:

Site Tours on 01st and 02nd July 2021

Records of destruction of printed waste by Accrued plastics cert of destruction dated 26.09.2018

Blackburn Waste CBDU 87670 expiry 14.02.2022

Biffa waste Service CBDU 104360 expiry 23.05.2022

4.11	Pest management

Pest control management system is carried out by Premier Pest Control BPCA M15/ 683 expiry 28.02.2022 under 2021 contract. Premier Pest Control are contracted to provide 8 routine, 4 Biologist and 4 EFK (including annual tube change) visits, defines the responsibilities of the site and contractor and the schedule covers rats, mice, crawling and flying insects. A Site-Specific Risk Assessment survey is carried out annually. Pest control equipment was appropriately located and operational at the time of the assessment and no evidence of any pest infestation observed during the audit tours. The buildings are well proofed with no potential access points noted during the audit. The site ensures the risk of pest infestation on the site is minimised by using the services of a competent pest-control contractor. The pest control contract stipulated an immediate call out service in the event of an infestation. In the event of rodent activity, the service provides follow-up until clear. Employees are trained to recognise the signs of pest activity and any instances noted would be reported and recorded and is covered in hygiene training. In the event of infestation immediate action is taken to eliminate the hazard and action taken to evaluate any contamination risk to the product which is checked prior to release. Reviewed analysis for 2020/1 and showed low external activity across baits and issues were monitored until clear with no internal pest incidents reported. There is a site plan showing locations of internal and external non-toxic baits and was signed and dated. Visits were up to date and completed by trained technicians. The pest control data shows no cause for concern and no birds or flying mammals issues raised. No open loading bays and door management is used to prevent birds entering the site. The last routine visits showed no external activity and no concerns or proofing issues were reported. Training records were reviewed for the technician and safety data sheets were available for all chemicals used. There are nontoxic internal bait points and external nontoxic.

Audit Evidence:

Premier Pest Control BPCA M15/ 683 expiry 28.02.2022 and 2021 contract
Viewed service reports dated 28.01.2021 and 28.04.2021 no activity reported
2021 Bait Plan dated 28.01.2021
Pest Risk Assessment and Follow up Procedure dated 10.07.2020
Technician CC RSPH Level 2 Cert in Pest Control dated 27.03.2013
Biologist Service Visit report dated 02.06.2021 with no recommendations and no concerns raised
MSDS Ratimor Fresh Bait
2020 and 2021 Trend analysis for Pests with no significant activity
Site Tours on 01st and 02nd July 2021

Non-applicable clauses	4.1.5 no raw materials stored outside, 4.2.2 no suspended ceilings, 4.2.3 no internal drains, 4.2.4 no windows pose a risk, 4.2.6 no elevated walkways, 4.3.2, water, air, steam, ice or other gasses don't contact product, 4.4.3 no external tanks/silos, 4.7.7 no workshop, 4.8.5 no environmental monitoring, 4.9.2.4 no open noticeboards, 4.11.3 site does not undertake its own pest control

5.	Product and process control
5.1	Product development

Covered under HARM, SOP001 Design & Quotation Procedure and Flowchart at issue 8 dated 30.07.2019, SOP001/1/2/3 Design & Quotation Briefs and Quotes Flowcharts, SOP005 Order Process and Contract Review Procedure at issue 7, dated 08.04.2021 and SOP20 Trial Reel Procedure at issue1, dated 06.06.2019 using SOP002-1 Flexo Print Order Acknowledgement, SOP002-1-1Flexo Print Specification, SOP002-2 Gravure Print Order Acknowledgement, SOP002-2-1 Gravure Print Specification, SOP002-3 Flexo Pouch Print Order Acknowledgement, SOP002-3-1 Flexo Pouch Print Specification, SOP002-4 Gravure Pouch Print Order Acknowledgement, SOP002-4-1 Gravure Pouch Print Specification and SOP002-5 Print Order Progress Sheet. The site does not design and develop products in isolation, it advises customers on appropriate standard films and products and receives, and processes supplied print artwork to the pre-agreed customer specification. The site clearly defines when a trial is required and is documented. Trials are generally undertaken at the customers site to test the material in use during production. The site employs a specialist technical engineer to carry out the investigations with the customer to ensure the product is correct and meets safety and legal requirements. Changes to artwork are managed through the print order procedures with customers attending press passes at the outworker and proofs signed and retained by the site. Specifications for raw materials are established and agreed and Technical Specifications are created for all finished products. Specifications include critical use parameters such as materials, size, colour and functionality and artwork and specification are submitted for client approval. Each product is allocated a unique detailed product specification when the product is first manufactured. Samples are retained in line with customers' requirements. Any changes to design requirements are approved by the customer. Any changes to existing products are approved by the customer and a new unique reference generated. Production is carried out under defined operating procedures to produce a safe and legal product. The procedures ensure the validation of accuracy of data, how changes to specifications are updated and communicated, any testing requirements, capturing process data on any plant trials and any effect on the technical specification

Audit Evidence;

Reviewed as part of vertical audit for new product artwork ref 210329 approved on 15.03.2021, customer order and order acknowledgment viewed , specification PP-COO324-01 V1 Item Number 220430 generated, checked and approved using SOPD2-4 Print Order Check Sheet, and specification sent to TLC on 10.03.2021 BOL 1563, printed

product goods in checks carried out on delivery note number DN470929 on 29.03.2021 and goods out checks for delivery to customer DN2035 on 02.04.2021 and competed SOPD2-4 Print Order Check Sheet
Very little new product development taken place during the last 12 months has taken place due to Covid-19 issues other than new print designs
Viewed visit reports for onsite customer trials of products in use on customers machinery dated 05.02.2021, 15.03.2021 and 30.03.2021
5.1.2 Product Trials RA- BRC6-0029 dated 2021
Site Tours on 01st and 02nd July 2021

5.2	Graphic design and artwork control

Covered in HARM, QMS 032 Graphic design & artwork control policy at issue 4, dated 07.10.2019, SOP02 print order new design at issue 9, dated 01.04.2021 and SOP03 print order repeat design at issue 9, dated 01.04.2021 to manage changes to artwork. Artwork file are provided by the Customer via email or FTP link, in house systems ensure artwork is checked and a final approval from the customer received prior to sending the job to print at outworkers. All new jobs are given a unique reference number. The printed product is checked by the customers champion and recorded on print order progress sheet for any new or existing printed product. Checks are carried out using approved artwork on receipt of materials from printers prior to despatch to ensure no loss of essential information or mixing of products Print equipment is uniquely numbered and appropriately stored and plates may be supplied by the site or through the outworker. The site has a policy to address requirements for renewal of approved masters, as necessary. Artwork files are held on the server, are protected from malicious intervention and backed up daily.
Audit Evidence;
Reviewed process and procedures with Technical Customer Champions JP and RS during site tours for Gravure Print Order Specification sheet ref 42N055PPP, SOP002-5 Technical Champion Check sheet completed on 01.07.2021, SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021, Printer Hatzpoulos order confirmation 10.06.2021,Technical Data Sheet for product dated 11.06.2021 and approved artwork and for purchase order and customer SA artwork approval dated 13.05.2021, item Code PO346, SOP-002-1-1 flexo print order specification sheet code PO-C00285-086-V1, and SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021 and SOP002-5 Technical Champion Check sheet completed on 01.07.2021
Site Tours on 01st and 02nd July 2021

5.3	Packaging print control

No Packaging printing

5.4	Process control

Covered under and HARM and SOP010 Production Control at issue 10, dated 04.01.2021 and recorded on production record sheet SOP010.1, products in process checks SOP010.2 and SOP60 Line Clearance. The site has used hazard and risk principles to determine process control measures to manage defects and quality. Defect checks include dimensions, perforations and foreign bodies as examples with checks carried out on start-up and during the run by operators. Outwork print checks are carried out following SOP02 print order new design at issue 9, dated 01.04.2021 and SOP03 print order repeat design at issue 9, dated 01.04.2021. Machines process control is PC recipe control through the new Radius MIS system and all processes viewed were operating within tolerances and under control. Speeds, pressures and perforation are example of controls used. The site procedures in place ensure effective control of all operations relating to critical product defects with GMP procedures and robust prerequisites programmes to ensure production of safe and legal products that meet customer requirements. All products have a pathway to the specification and process control parameters defined. There is a unique item code on the MIS system for each product

used to generate a Works Order which contains all relevant information to run the job. The work orders contain materials, customer requirements and process equipment settings. This information provides detailed instructions to the operators to manufacture the product through all stages of production. The bill of materials is on the works order and defines materials and packaging and labelling instructions. Specifications are approved by QA/Sales and the Technical Engineer. All production runs are inspected by operatives during the production process. Process checks are carried out at start up and hourly during the run. New specifications are raised after an approval process with the customer under the NPD procedure and quality procedures are then validated to ensure conformity to specification and are verified via in-process inspection regimes. There is a robust control of non-conforming product procedure in place. Defective materials are removed at all stages of production. All processes were in control and operating within the defined process capabilities and line clearance recorded. Line clearance include roles of persons involved, areas where material can become trapped, validation of line clearance and sign off for continuing production

Audit Evidence;

Reviewed specifications, bills of materials, production QC records and line clearance records for Machine K1 work order 202467 with operator DH slitting reel ref 3922, K2 work order 202317-2 with operator TB slitting reel ref 7199, Eldec 3 work order 201711 with operator SH slitting reel ref 320126535, Eldec 3 201603 work order 201603-2 with operator GJ and machine S37 Work order 202544 with operator CA during site tours on 01st and 02nd July 2021

Reviewed process and procedures with Technical Customer Champions JP and RS during site tours for Gravure Print Order Specification sheet ref 42N055PPP, SOP002-5 Technical Champion Check sheet completed on 01.07.2021, SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021, Printer Hatzpoulos order confirmation 10.06.2021,Technical Data Sheet for product dated 11.06.2021 and approved artwork and for purchase order and customer SA artwork approval dated 13.05.2021, item Code PO346, SOP-002-1-1 flexo print order specification sheet code PO-C00285-086-V1, and SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021 and SOP002-5 Technical Champion Check sheet completed on 01.07.2021

Site Tours on 01st and 02nd July 2021

5.5	Calibration and control of measuring and monitoring devices

Covered under SOP008 Control of Inspection Measuring and Test Equipment Procedure at issue 5, dated 13.05.2021, SOP008.1 Calibration Register at issue 4, dated 24.11.2017 and 5.5.2 Calibration and control of measuring and monitoring devices RA-BRC6-027 dated 23.04.2021. The site identifies the control of off-line measuring equipment used to monitor control points which identifies the location, equipment, identification code and calibration due date. The equipment is only used by authorised personnel and protected against damage and adjustments from unauthorised personnel. The Quality Manager is responsible for ensuring the relevant people within the organisation carry out calibrations in line with the relevant legal requirement or standard for the equipment. In event of failure, products made since the last clear point would be re-evaluated and any out of specification items rejected under the Control of non-conforming product procedure. Equipment is calibrated externally by recognised Calibration Houses using equipment traceable to national standards.

Audit Evidence:

SOP008.1 Calibration Register at issue 4, dated 24.11.2017 and Calibration by D Brash of TCS scales viewed on site tours cert numbers 129372 and 129371 dated 15.04.2021 and Standard Calibration Services of micrometre cert 309939

Site Tours on 01st and 02nd July 2021

5.6	Product inspection, testing and measuring

Covered under HARM, SOP010 Production Control at issue 10, dated 04.01.2021 and 5.6 Product Inspection RA-BRC6-028 dated 07.06.2021. No in- line testing is deemed necessary. Checks recorded demonstrate that the finished product is within the tolerances laid down in the agreed product specification and conforms to legal requirements. The

frequency of checks is in accordance with industry-accepted practice, customer requirements and is based on risk analysis. All incoming material are inspected by the stores personnel prior to acceptance and use. Quality checks are conducted by trained operators evidenced in a review of training records. The job sheets contain the specifications and product inspection routines. Quality checks carried out by the operators during production include dimensions, visual appearance and hole sizes as examples. Checks are recorded on production record sheet SOP010.1, products in process checks SOP010.2 and SOP60 Line Clearance. All pallets delivered to the finished goods warehouse carry a Q.C. Pass sticker which has been signed by the Production Operative. Where testing shows out-of-specification results, a documented procedure for investigating these results is established and followed to determine whether the cause is nonconforming product or a testing failure under the non-conforming product procedure. Test methods, analytical methods and customer-approved reference samples are the most recent version, validated for sensitivity through calibration by third parties and available in production. Quality checks are conducted by machine operators trained to conduct standard tests. New specifications are raised after an approval process with the customer. The quality procedures are then re-validated to ensure conformity to specification and are verified via in-process inspection regimes and operators re-trained where necessary. Samples used for testing are disposed as waste. Migration Testing is carried out by the site suppliers

Audit Evidence:

Reviewed specifications, bills of materials, production QC records and line clearance records for Machine K1 work order 202467 with operator DH slitting reel ref 3922, K2 work order 202317-2 with operator TB slitting reel ref 7199, Eldec 3 work order 201711 with operator SH slitting reel ref 320126535, Eldec 3 201603 work order 201603-2 with operator GJ and machine S37 Work order 202544 with operator CA during site tours on 01st and 02nd July 2021

Reviewed process and procedures with Technical Customer Champions JP and RS during site tours for Gravure Print Order Specification sheet ref 42N055PPP, SOP002-5 Technical Champion Check sheet completed on 01.07.2021, SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021, Printer Hatzpoulos order confirmation 10.06.2021,Technical Data Sheet for product dated 11.06.2021 and approved artwork and for purchase order and customer SA artwork approval dated 13.05.2021, item Code PO346, SOP-002-1-1 flexo print order specification sheet code PO-C00285-086-V1, and SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021 and SOP002-5 Technical Champion Check sheet completed on 01.07.2021

Raw Material Supplier Polivouga Declaration of Compliance dated 14.08.2020 confirming compliance to documented relevant legislation and Amplas migration test report ref 18/0115 with results well within the migration limits laid down in the EU10/2011 directive. Specifications include functional claims and reference intended use of packaging, functional properties, include reference to the standard test methods used and limits/tolerances and are agreed with the customer as part of the acceptance procedures and issued from suppliers as part of the film specification

Site Tours on 01st and 02nd July 2021

5.7	Control of non-conforming product

Control of non-conforming materials is included in the site HARM study, SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021 is part of the food defence plan and understood by all personnel. Any suspect product is labelled and quarantined awaiting disposition i.e., scrap or concession recording root cause and corrective action. Any defective product is recorded on a log and Radius MIS. Returned product is also recorded and labelled on hold. NCRs reviewed and reported as part of annual review. No non-conforming materials observed on the site tour.

Audit Evidence:

NCR Log and SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021

SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020

Site Tours on 01st and 02nd July 2021

5.8	Incoming goods

Covered under HARM, SOP 011 Materials Handling and Storage at issue 13, dated 21.04.2021, 5.8 Incoming Goods RA-BRC6-028 dated 07.06.2021, Vulnerability Risk assessments and is included in the site food fraud and defence system. All raw materials are recorded and checked on arrival with date, batch number, who received the product, supplier, seal number and delivery note number. All incoming raw materials and pallets are checked by warehouse personnel for taint, odour, contamination & damage and if acceptable the delivery note is compared against the PO, signed. After checking the vehicle hygiene standards are acceptable the material is unloaded. Any non-conforming product identified initiates the non-conforming goods procedure. Any discrepancies on quality are recorded on delivery note and if raw materials do not meet the standard the item is quarantined using the non-conforming materials procedure and the quality manager is informed. Materials are booked into stock and used on FIFO basis. No raw material testing is deemed necessary. All raw material complaints or defects identified by the site are recorded and investigated including root cause analysis. Unloading areas for deliveries are clearly identified and designed to prevent product mix-ups with sufficient space available. The site procedures validate all raw materials and intermediate products prior to their introduction to the process through the issuing of materials to production and production checks. Supplier performance is monitored and reviewed at annual management reviews.

Audit Evidence:

NCR Log and SOP013 Customer Complaints, Control of Non-conforming Product and Corrective action Procedure at issue 13, dated 08.04.2021

SOP 12.5 Quality Management Review at issue 9, dated 04.09.2020, Management Review Meeting Minutes dated 24.09.2020

Site Tours on 01st and 02nd July 2021

Reviewed procedures with warehouse operator JE and customer champions and correctly completed goods in and printed product checks for purchase order 1563 delivered on delivery note 14564 dated 15.12.2020 reel ID 2877665, printed product goods in checks carried out on delivery note number DN470929 on 29.03.2021, Gravure Print Order Specification sheet ref 42N055PPP, SOP002-5 Technical Champion Check sheet completed on 01.07.2021, SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021 and for purchase order and customer SA artwork approval dated 13.05.2021, item Code PO346, SOP-002-1-1 flexo print order specification sheet code PO-C00285-086-V1, and SOP0011-1 Printed Film Checking Sheet completed on 01.07.2021 and SOP002-5 Technical Champion Check sheet completed on 01.07.2021. Viewed goods in checks for raw material PO012712 ref 4021/4022 on 1st July 2021

5.9	Storage of all materials and intermediate and finished products

Covered under HARM, SOP 011 Materials Handling, Storage and Despatch at issue 13, dated 21.04.2021, 5.9 Storage RA-BRC6-031 dated 24.05.2021, Vulnerability Risk assessments and is included in the site food fraud and defence system which are trained out, understood by the relevant staff, and implemented. All deliveries are recorded on arrival detailing date of arrival and supplier. WIP was observed to be appropriately protected. Material for recycling is stored appropriately. No hazardous chemicals. During the audit, it was observed that raw materials and finished product were stored off the floor and away from walls. No pallets stored outside.

Audit Evidence:

Site Tours on 01st and 02nd July 2021

5.10	Dispatch and transport

Covered under QM037 Transport Policy at issue Despatch of product QMS082, SOP 011 Materials Handling, Storage and Despatch at issue 13, dated 21.04.2021, 5.10 Despatch RA-BRC6-032 dated 28.06.2021, Vulnerability Risk assessments and is included in the site food fraud and defence plan. All finished products are stored internally in warehouses. Finished products were observed to be appropriately labelled, protected and controlled to prevent

contamination or malicious intervention and appropriately wrapped for distribution. The product is shipped from site by third party hauliers. Wooden pallets used in the process are inspected prior to use and are sound, dry, clean and free from damage/contamination. Any damaged, contaminated or unacceptable pallets are rejected, not used and reported to management to facilitate disposal. No site owned vehicles used for deliveries. Delivery drivers are supervised whilst on site, have access to toilets, not allowed into production and must abide by the site hygiene rules. Delivery vehicles are visually checked by the W/house and condition is recorded. The site use contract hauliers and there are transport supply agreements in place.

Audit Evidence:

Site Tours on 01st and 02nd July 2021

Pink Link haulier signed agreement for distributing food contact packaging securely and hygienically dated 05.09.2019 and ADD Express agreement documenting requirements for transporting food packaging dated 16.09.2019. Goods out checks for delivery to customer DN2035 on 02.04.2021 and competed SOPD2-4 Print Order Check Sheet

Non-applicable clauses	5.3 No printing, 5.6.3/6 no in line testing, 5.6.9 no vision equipment, 5.6.10 No subcontracted analysis, 5.9.5 no packaging stored outside, 5.9.7 no hazardous chemicals 5.10.4 no company vehicles

6.	Personnel
6.1	Training and competence: raw materials handling, preparation, processing, packing and storage areas

Covered under QM 039 Training Policy at issue 4, dated 20.10.2020, SOP07 Training and recorded on training matrix SOP07.4 maintained by the Quality Manager The site has an excellent training programme to ensure staff are fully trained and supervised and competency is assessed through demonstrating tasks. The site supports and funds all training both job related and general interest to broadly enhance staff skills. New employees are subject to an induction program that covers all BRCGS requirements. All employees are trained in the company's hygiene regulations as part of their induction training. Training is implemented in accordance with the Training Matrix used to confirm competence and identify training needs for each employee. Viewed training for operators that identifies competency level and any dates for planned refresher training. Training records are maintained. Training is recorded onto a record which details type of training, signature of trainee and trainer and date of training. 2021 Training records for Line clearance, production control and print order new design do not include the duration of training and was raised as a non-conformance. The site training procedures ensure new or changed procedures, working methods and practices related to product safety or quality are communicated to relevant personnel and are added to the training matrix. Training is through on-the-job training directly linked to standard operating conditions. All staff interviewed during the evaluation were competent, trained, demonstrated competence and were aware of the need to challenge unknown visitors as part of the food defence plan. In depth training is provided by machine manufacturers for new equipment for the machine operators. Training records for all personnel are kept for the life of the employee and indefinitely if the employee leaves the site.

Audit Evidence:

Site 2021 Training Matrix

Operator TB Food hygiene Level 1 and HACCP level 2 by Advanced Food Safety on 02.11.2018, Site Security and Food Defence training by Technik on 11.06.2019 and workwear policy and plant hygiene policy training on 17.06.2021

JP Technical Customer Champion training Basic Food Hygiene by Verner Wheelock on 15.07.2020 Site Security and Food Defence training by Technik on 23.06.2019, SOP002/3 Print Order Training on 12.04.2021 and Personal Hygiene and Jewellery training on 18.06.2021

RS Technical Customer Champion Food Hygiene training by Advanced Food Safety on 29.04.2021 and plant hygiene policy training on 09.03.2021

Site Tours on 01st and 02nd July 2021

NC2 Clause 6.1.5 2021 Training records for Line clearance, production control and print order new design do not include the duration of training

6.2	Personal hygiene: raw materials handling, preparation, processing, packing and storage areas

Covered under 6.2 Personal Hygiene/ Staff Facilities/medical Screening RA-BRC6-026 dated 24.05.2021, QM12 personal hygiene and jewellery procedure at issue 5, dated 27.04.2021, QM012.3 Hand Washing Procedure at issue 1, dated 20.10.2020, QM018 Plaster Issue and Control Policy at issue 4, dated 09.09.2020 and plaster issue record QM10.1 which is trained out to all staff during induction. Full inspection of all facilities was carried out and all staff were observed to be correctly procedures. Hygiene Information is displayed on entry notice at reception & prior to site entry. Jewellery is not allowed to be worn in production areas other than a plain band ring (no stones) or medical alert jewellery. No mobile phones or electronic devices are permitted unless authorised. Personal items, food and medicines are not allowed in food packaging production areas and must be stored in personal lockers. Hand washing required, at entry to production areas for all staff and visitors plus hand sanitising gel dispensers at entry points. No false nails, excessive perfume/aftershave or nail varnish. Blue plasters are issued by the supervisor or first aider, controlled, stored securely and recorded. Eating is only allowed in canteen which was hygienic. Visitors follow the same procedures and gloves are available if needed and replaced regularly. Compliance to hygiene rules is carried out through internal audits and via line managers. Good hygiene practices were observed during the audit and no issues identified

Audit Evidence:

Site Tours on 01st and 02nd July 2021

Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed

6.3	Staff facilities

Covered under 6.2 Personal Hygiene/ Staff Facilities/medical Screening RA-BRC6-026 dated 24.05.2021. Full inspection of all facilities was carried out and all staff were observed to be correctly following the procedures during the assessment. Staff facilities were observed to be sufficient for the number of employees on site. There are fob controlled employee entrances with access to the canteen, locker rooms and toilets before production. Lockers are divided for personal items, work clothe and shoes. Clean and dirty clothes were observed to be are segregated. Hand-wash facilities provided with signage, stainless-steel sinks and sufficient hot water at the entries to production. Hand-washing advisory signs to prompt use are in all toilets and contain a sufficient quantity of water at a suitable temperature, unscented liquid soap and adequate hand-drying facilities. Eating, drinking and smoking are not allowed in locker and changing rooms or production and storage areas and non was seen. Food must be stored in fridges in canteen or in sealed lunch boxes. The canteen was in good condition and hygienic. Blue plasters are used, stored securely and logged. There are external smoke points outside. E-cigarettes are not permitted in production or storage areas. Toilets do not open directly onto production. Visitors are provided with coats and disposable hair covering. Compliance is carried out through internal audits and via line managers.

Audit Evidence:

Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed

Site Tours on 01st and 02nd July 2021

6.4	Medical screening

Covered under 6.2 Personal Hygiene/ Staff Facilities/medical Screening RA-BRC6-026 dated 24.05.2021 and induction training. Visitors must complete a health questionnaire upon entry to the site. In the event of absence employees attend a return-to-work interview with the line manager and trained out during induction training. All personnel must report if they have been in contact with any infections, diseases etc. workers returning to work after illness are required to fill in a return to work from sickness form. Effective Covid 19 precautions are in place. Any cuts and grazes are covered with blue plasters and are logged.

Audit Evidence:

Site Tours on 01st and 02nd July 2021

6.5	Protective clothing

Covered in the HARM and 6.5 Protective Clothing RA-BRC6-034 dated 24.05.2021. Clothing is permitted to be worn between all departments and personnel change into issued workwear at site. Suitable & sufficient protective clothing provided. Changing procedure are covered in policy as well as self-laundry guidelines used as a backup if needed to the third-party laundry services provided by Ellis. The site protective clothing covers the upper torso and does not contain external pockets or sewn on buttons. There is a locker for every employee and effective segregation of workwear was evident with clean and dirty clothing segregated. Hair nets and beard snoods are worn. Gloves are worn if required and disposed of after use. Safety shoes are provided and these are stored in the locker rooms provided. Blue metal detectable plasters are used for cuts / grazes and are recorded and managed. Visitors to production areas are required to wear coats and hairnets/snoods. Compliance to procedures is carried out through internal audits and via line managers

Audit Evidence:

Reviewed GMP audits SOP23 dated 25.02.2021, 28.01.2021, 26.05.2021 and 23.06.2021 including internal and external issuers comprehensively documenting conformity and all issues identified documented as closed

Site Tours on 01st and 02nd July 2021

Ellis Laundry site audit supplier questionnaire dated 22.10.2019

Non-applicable clauses	None

Requirements for traded products

7.1	Approval and performance monitoring of manufacturers/packers of traded packaging products
N/A	
7.2	Specifications
N/A	
7.3	Product inspection and laboratory testing
N/A	
7.4	Product legality
N/A	
7.5	Traceability

N/A	
Non-applicable clauses	7.1-7.5 No Traded goods

Additional Module: Plastic Pellet Loss Prevention	
10.1.1	Senior management commitment and control improvement
Click or tap here to enter text.	
10.2.2	Hazard analysis and risk assessment
Click or tap here to enter text.	
10.3.5	Internal audits
Click or tap here to enter text.	
10.3.6	Corrective and preventive action
Click or tap here to enter text.	
10.3.13	Management of incidents
Click or tap here to enter text.	
10.4.2	Building fabric and interiors: raw materials handling, preparation, processing, packing and storage areas
Click or tap here to enter text.	
10.4.4	Site security
Click or tap here to enter text.	
10.4.5	Layout
Click or tap here to enter text.	
10.4.8	Housekeeping and cleaning
Click or tap here to enter text.	
10.4.10	Waste and waste disposal
Click or tap here to enter text.	

10.5.8	Incoming goods
Click or tap here to enter text.	
10.6.1	Personnel: training and competence
Click or tap here to enter text.	
Non-applicable clauses	Click or tap here to enter text.