NO MATTER WHAT
THE FUTURE HOLDS

DATWYLER

Global Supplier Quality Agreement

Contents

1 Introduction and Objective

1.1 Introduction

We, Datwyler Sealing Solutions (“Datwyler”) are committed to being the supplier of choice of our customers in all business segments, by providing superior products while displaying excellence in quality, innovation, delivery, service and competitiveness.

Our suppliers play a very important role in supporting us fulfilling the very high expectations of our customers. The quality of our products is dependent on the quality of the products and services that we purchase from our providers. Our objective is therefore to purchase quality products and services with an above-average cost-to-benefit ratio.

Datwyler plans to maintain its business strength by working closely and on a long-term relationship together with its supply base, also in order to assure that our and our customer’s expectations and requirements are clearly understood and translated into a work environment of continuous quality improvement.

In order to achieve this objective, it is essential for our suppliers to have an effective quality management system in place. This binding agreement is the basis for our cooperation. The Supplier Quality Agreement comprises mandatory stipulations together with further individual agreements, which may be negotiated separately, if needed.

This quality agreement is part of each purchasing contract for products and services which undergo further processing at Datwyler or which are sold through us.

The provider performance will be closely monitored and the provider status will be results based.

All requirements in this agreement are to be considered as “Customer Specific Requirements”.

This agreement is read in conjunction with the applicable Supply Agreement and/or the agreed Technical Specifications, as appropriate.

1.2 Objective

Our goal is to be the benchmark leader with regard to quality, costs, readiness to deliver and customer focus. We consistently pursue the implementation of a 'zero defects' objective, in order to comply 100% with delivery deadlines and quantities supplied.

This Supplier quality agreement is a written and formal agreement concerning quality responsibilities and activities between both parties in order to achieve these goals.

2 Responsibilities

The responsible contact partner for suppliers is either the local purchasing department or, if available, the global lead buyer. Datwyler has globally responsible lead buyers in place for the following spend categories:

- Raw materials for rubber compounds
- Metal or plastic parts (so called ‘inserts’)
- Externally sourced rubber compounds

- Packaging and GMP-critical (Good manufacturing practice) indirect materials (so called 'processing aids')
- Transport
- Aluminium and Polypropylene

Lead buyers are the main contact point for the providers and they have the competency to negotiate in respect of inquiries, agreements, prices and contracts.

The division of responsibilities between the Datwyler and the provider is described in detail in chapter 28.

3 General terms and conditions

This agreement comes into effect when signed by both parties. The agreement shall remain valid as long as the supply agreement remains valid or products and services are supplied. It supersedes all prior agreements, negotiations, statements and writings relating thereto.

Amendments to this agreement may be made only by mutual written agreement.

The attachments to this agreement may be updated independently from the core of this agreement providing approval from both parties (see chapter 30). The revised attachment versions become part of the agreement.

Both parties will identify key contacts for the involved departments and provide contact information for all technical and/or quality issues. The list of the key contact personnel can be found in Attachment xx.

4 Quality management (QM) system and certification status

Datwyler's quality management system meets the actual requirements of the following global and/or segment-specific norms:

- ISO 9001
- IATF 16949
- ISO 15378

We reserve the right to verify the provider's system by means of audits.

The provider and/or manufacturer shall grant Datwyler (and also, with the agreement of Datwyler, the latter's customers) access to all operating facilities, test centres, stores and adjacent areas, and shall allow said parties to inspect all documents relevant to quality. Necessary and appropriate restrictions on the part of the supplier in order to protect his business secrets shall be accepted for this purpose.

Datwyler requires to be provided with actual copies of the valid certificates and to update them unasked after a change.

4.1 Automotive segment

Our minimum requirement for automotive suppliers is to maintain a certification according ISO 9001 issued by an accredited certification body, unless otherwise specified by Datwyler's customer.

The suppliers of automotive products and services are requested to develop, implement and improve a quality management system (QMS) with the ultimate objective of becoming certified to IATF 16949 by applying the following steps:

a. certification to ISO 9001 through third-party audits
b. certification to ISO 9001 with compliance to other customer-defined QMS requirements through second-party audits
c. certification to ISO 9001 with compliance to IATF 16949 through second-party audits
d. certification to IATF 16949 through third-party

Furthermore, and as required by Datwyler's customers, the requirements of AIAG (American Automotive Industry Action Group), VDA (German Automotive Industry Association) and further Customer Specific Requirements (these CSR can exceed the requirements mentioned in this agreement) shall be taken into account.

4.2 Health Care segment

The provider's quality management system will meet the relevant national and international quality standards and regulations.

The implementation and practicing of GMP rules in all process steps at the provider's production facilities is strongly recommended.

5 Code of Conduct

Datwyler demands that providers and sub-contractors adhere to the same set of standards that Datwyler sets for itself.

For this reason, Datwyler introduced the Supplier's Code of Conduct. It is required that the Supplier Code of Conduct is signed by the provider before a delivery of products or services can take place.

6 Specifications

The provider agrees to supply the products listed in attachment xx, in accordance with the agreed specifications. These specifications can be based on the technical specifications of the product or be defined in bi-lateral agreements.

Any proposed specification change must be communicated and approved by all of the affected parties of this agreement.

Responsibilities regarding specifications are listed in chapter 28 'roles and responsibilities' of this agreement.

7 Ensuring quality prior to serial deliveries

7.1 Feasibility

Before concluding a contract, the provider verifies whether the requested product can be produced and delivered in the required quality and quantity, adhering to specified deadline(s).

It is the provider's obligation to discuss unclear requirements with Datwyler's purchasing department/Lead buyer in advance and to obtain any additional information that might be needed. This also includes the definition and handling of critical and significant product characteristics.

If corrections to the specifications are required due to the feasibility study, Datwyler's purchasing department/Lead buyer must also be informed. Changes shall be handed in written form and shall be agreed in advance with Datwyler.

7.2 Quality planning

The quality of products and services is mainly defined during its development. It is therefore necessary for the provider to apply appropriate preventive methods of quality planning at the development stage (e.g. APQP). These measures shall include the elements as described in the sections 7.3 to 7.14.

7.3 FMEA for design and processes

The Failure Modes and Effects Analysis (FMEA) is an important instrument to prevent defects. This methodical procedure enables the causes of potential defects to be identified at an early stage so that suitable measures can be taken.

A Design FMEA is required for all products for whose design the supplier is responsible.

Process FMEA's shall be carried out for all new and modified production processes.

7.4 Test planning

Test planning shall stipulate:

- - which feature needs be tested,
- - how often,
- - to what extent,
- - by whom,
- - with which test equipment, and
- - how,
- - how the results have to be documented.

The results of the test planning shall be summarized in a Test Plan.

7.5 Planning of test equipment

Planning of test equipment (both, in quality lab and on shop floor) to secure serial production conformity shall stipulate the type, quantity and accuracy of the requisite test equipment.

Measurement system analyses (e.g. according QS 9000) shall be carried out on the selected test equipment to ensure that process assessment is possible based on measured values.

The supplier shall have a test equipment monitoring system.

7.6 Planning of processes and operating equipment

Production processes and operating equipment shall be planned and developed in such a way that with an adequate capacity, they are able to produce the required features and characteristics within the agreed specifications.

Results of process planning shall be presented in a process flowchart, being the basis for the process FMEA and test planning.

The capability of operating equipment and processes shall be proven. The minimum requirement for provisional process capability is Ppk ≥ 1.67 and ongoing process capability is Cpk ≥ 1.33.

Unless agreed otherwise, at least 125 measured values shall be available, originating from a production run of at least 300 parts, for the calculation of the provisional process capability. The calculation of ongoing process capability is only permitted after a suitable number of production days.

7.7 Packaging and cleanliness

Packaging shall be specified in such a way that damage is prevented during handling, transport and storage.

In addition to the aspect of convenient handling (filling quantity, convenient emptying, transportability and stack ability), environmental aspects shall also be taken into account.

If Datwyler does not set a specific requirement for packaging, it is the provider's duty to agree on the packaging specifications with Datwyler Purchasing prior to serial delivery.

The provider undertakes to deliver finished products without contamination, in dry conditions and with a standard of cleanliness which conforms to the general state-of-the-art.

The shipping of material shall be performed according to the conditions defined through the contractual specifications with Datwyler.

7.8 Prototypes / development types

The manufacturing processes for prototypes may differ from the serial manufacturing process.

These alternative processes shall be agreed with Datwyler. The required documentation may be taken from Datwyler’s prototype and development orders. This documentation shall be delivered together with the parts, without a request to do so, and shall be sent to the purchasing department in advance by e-mail.

7.9 First samples

As a general rule, first samples are always required prior to serial production. First samples are those samples (of products or materials) which were produced with serial equipment, under serial conditions and with the staff envisaged for serial production. They are used to prove, prior to serial deliveries, that quality requirements are met.

First samples are required for new or modified products, with information about the quantities required and the date of receipt. All quality characteristics, as agreed in the specifications, shall be taken into account for this purpose.

After an interruption of more than 12 months of parts deliveries, a new first sampling / re-qualification test is required. This procedure for production process and product release shall also be applied to sub-contractors.

Sampling shall be carried out according to the production process and product release procedure as per PPAP Level 3 (Production Part Approval Process), unless agreed otherwise in writing.

7.10 IMDS data entry (Automotive segment)

The relevant material entries in IMDS (International Material Data System) shall be added to the sampling documents.

Regulations governing, when a sampling process shall be carried out, are stated in VDA Volume 2, or in separate individual agreements.

7.11 Reference samples (Health Care segment)

The manufacturer will store product reference samples for each batch manufactured according to their Quality Management Standard Operation Procedures (SOP's).

Samples of starting materials (other than solvents, gases or water used in the manufacturing process) shall be retained for at least two years after the release of product.

The reference sample should be of sufficient size to permit the carrying out of at least 2 full analytical controls.

Reference samples should be representative for the batch of starting material, intermediate product or finished product from which they are taken. Where a manufacturer closes down and the manufacturing authorization is surrendered, revoked, or ceases to exist, the reference samples shall be transferred to Datwyler.

7.12 Hazardous substances

Prior to the first delivery of hazardous substances, the relevant material safety datasheets shall be sent to Datwyler's purchasing department/Lead buyer without a request to do so.

7.13 Preventive maintenance

The manufacturer shall prove that he has at his production facilities a system for and carries out preventive maintenance.

7.14 Training

The provider's employees shall be qualified (adequate knowledge, experience, qualification and competency) for the tasks they need to perform in carrying out the obligations as required in this quality agreement. This shall be ensured by appropriate internal or external training. Training's shall be documented for each job description:

- documenting completed training
- required re-training
- evaluation of the training process effectiveness
- signed by the trainer and trained personnel

Upon request, this documentation shall be presented, e.g. during audits.

7.15 Process documentation

The provider's and also sub-contractor's manufacturing process should be validated and documented.

8 Ensuring quality during serial delivery

8.1 Statistical process control

Statistical Process Control (SPC) is used as a process-based control instrument to identify deviations in the production process at an early stage and to intervene with the goal to correct the process before defective products are manufactured.

The manufacturer shall use appropriate quality control cards to prove that statistical process control is applied to all critical or significant characteristics that can be controlled. Datwyler is entitled to inspect these records at any time, on request.

If characteristics cannot be verified directly, SPC shall be applied in respect of process parameters which influence them. By its nature, this possibility is also available for product characteristics which can be verified, and should be preferred for clear correlations.

8.2 Acceptance tests

For product characteristics that do not reach acceptable capability levels within the statistical process control, the supplier shall conduct suitable quantitative and/or qualitative acceptance tests to guarantee error-free products. This shall be documented with appropriate acceptance cards or test reports.

8.3 Key performance indicators

For the purpose of process control, we expect our suppliers to define appropriate key performance indicators (KPI) for their production process of the product that is supplied to Datwyler. Together with the KPIs, target values have to be defined. The supplier shall record actual KPI data, visualize it and define appropriate improvement measures. The KPI's should be made available to Datwyler, on request.

8.4 Safeguarding incapable processes

For non-capable processes (Cpk < 1.33), suitable tests to safeguard quality shall be carried out with respect to the specified characteristics to avoid that Datwyler's production is disrupted by defective parts.

8.5 Test certificates

For each batch supplied to Datwyler, there shall be an appropriate laboratory/quality determination of satisfactory conformance to the agreed specifications, if applicable.

The provider shall supply released materials to Datwyler with a certificate of Analysis (CoA) or Certificate of Conformity (CoC). The CoA shall be signed by the Quality Assurance representative indicating that all requirements were met in accordance with pre-determined agreed upon specifications.

This certificate shall include standard values, the tolerances and the actual readings that have been measured. The documented product characteristics and sample size shall be agreed with Datwyler.

8.5.1 Automotive segment

We basically reserve the right to request one acceptance test certificate as per DIN EN 10204, 3.1 per delivery, in which the critical and significant product characteristics features shall be confirmed.

8.6 Expiration date

The manufacturer's expiration date will be assigned based on the supplier's experience. Any modifications to the established expiration date will be based on a shelf life protocol that will be written, approved, and executed. Data to support the assigned expiration date or re-evaluation testing shall be available upon request for review by Datwyler. In case the shelf life is not applicable, at least the manufacturing and/or release date shall be communicated to Datwyler on the certificate of Analysis (CoA) or Certificate of Conformity (CoC).

The provider shall deliver product to Datwyler using the FEFO (First-Expired-First-Out) method.

8.7 Product identification

Separate labels that fulfil specific criteria, shall be used to identify the packaging units. The shape of the label and contained information (e.g. name of the manufacturer, product reference, batch number, purchase order, name of the Datwyler site that placed the order, quantity) have to be defined together with Datwyler. The requirements for suitable traceability shall be taken into account for this purpose.

A batch number shall be recorded on the shipping order/delivery documentation.

In case of a quality complaint, traceability and clear containment of potentially defective parts/batches must be guaranteed.

Copies of the shipping order/delivery documentation must be archived at the provider's manufacturing plant and at the Datwyler site.

8.8 Emergency strategy / Force majeure

The provider's system shall be set up in such a way that an emergency strategy can be launched in case a delivery bottleneck would occur. The contingency plans for material supply due to these events shall be communicated to Datwyler and approved by Datwyler before any material is shipped.

The provider and/or manufacturer shall notify Datwyler of any significant event that may impact the supply of material to Datwyler, as soon as possible.

In case of risks of production shutdown at Datwyler or at our customer, due to delivery of products which are not conform to the specifications, the supplier shall liaise with Datwyler to remedy the situation by suitable immediate measures for which the supplier takes responsibility (spare parts deliveries, sorting work/reworking, special shifts, express transport, etc).

The supplier is responsible to ensure that serial deliveries are not interrupted under any circumstances. He shall also continue to be able to deliver in case of force majeure by means of any safety reserve stock that may be required.

8.9 Re-qualification test

All products delivered to Datwyler must regularly undergo a re-qualification check. At least all dimensions (if applicable) and tests according the product specifications have to be measured/performed. The frequency of re-qualification checks shall also be specified as part of the advance quality planning and shall usually be based on our customer's requirements. These specifications shall be incorporated into the production control plan.

If no special agreements are made about this point, a re-qualification shall be carried out at least once per year.

The requalification results shall be made available to Datwyler, on request, within 2 working days.

8.10 Process changes / Change notification

All changes to the product or the process chain require the written agreement of Datwyler. This relates to:

- composition/specification of the product
- changes to production processes, sequences and materials, including those made by sub-contractors
- change of sub-contractor(s)
- changes to test procedures and equipment
- transfer of production locations
- transfer of production facilities on site
- source of raw material
- its regulatory status

A change has to be communicated even if this has no impact on specifications which have been agreed upon by both parties, or in absence of such mutual agreed specifications.

These changes shall be notified to Datwyler within acceptable timeframes before the planned change, but at least 6 months ahead of time. In this way, resultant measures to achieve a release can be jointly coordinated. All necessary and the following information shall be provided in advance in such cases:

- risk assessment for the process change
- proof that the process sequences are ensured throughout the process chain.

All changes will need a written approval before they can be executed. Additionally, for certain important changes, a formal re-approval process by the customer will be necessary.

9 Deviation management

The provider shall utilize written procedures that document the process to be used in case of any deviations to material/process and for any performance related investigations. These procedures will include provisions to assure notification of appropriate personnel/management at Datwyler.

In case of deviations regarding the product specifications, the product shall not be delivered.

However, a derogation requirement, with sampling if required, could be asked to the Datwyler quality contact to accept the lot by concession.

In the unlikely event the provider discovers a deviation associated with a lot that has been already shipped to Datwyler, the provider will notify the appropriate Datwyler site quality contact within 1 working day after the discovery of the deviation.

Any root cause analysis, corrective action or preventive action identified as a result of the deviation will be documented and completed within the agreed timeline between both parties. This communication shall be made to all Datwyler sites to which the delivery was made.

10 Corrective actions / Reaction times for complaints

Datwyler expects its suppliers to track target values for key processes in production and administration, and to have action plans available to achieve these targets.

In case of complaints, we expect:

- a confirmation of receipt within 24 hours,
- a first written presentation of immediate measures within 48 hours,
- a final statement about the root-causes of the defects and corrective actions within 10 working days for the automotive segment
- a final statement about the root-causes of the defects and corrective actions within 15 working days for the Health Care segment

The documentation shall be prepared in an 8D-form or another form as agreed with Datwyler.

If requested, Datwyler will return complaint samples to the supplier for investigation and/or allow the supplier to visit and inspect the rejected lot(s) at Datwyler's premises. In case, the supplier would not be able to provide a complete 8D-report within the defined period, he shall notify it and provide a well-founded interim report including a planned completion date.

After 60 days or a time frame agreed with Datwyler (e.g. due to investment or significant modification to be implemented) , the supplier shall prove effectiveness of the taken corrective actions. In case, corrective actions would not be effective or if the supplier recognizes another problem, he shall inform Datwyler immediately.

11 Recall (Health Care segment)

The provider will immediately inform Datwyler in the event of any potential risks pertaining to products supplied to Datwyler.

Examples of potential risks could be but is not limited to:

- Incorrect labelling
- Deviations which may potentially impact the quality of the supplied product
- Critical contamination (microbiological, dirt, etc)
- Process changes which may reduce the quality of the supplied product
- Failure to ensure sterility

12 Statutory safety and environmental protection regulations

A process shall be in place to ensure compliance with all relevant statutory safety and environmental regulations. Proof shall be furnished by appropriate certificates or declarations of conformity.

It is responsibility of the provider to cascade all applicable requirements down his own supply chain in order to assure and to follow up that all sub-suppliers can and will respect these requirements.

13 Documents and records

Datwyler reserves the right to inspect all documents and records created in connection with products delivered or to be delivered to Datwyler. These documents will be retrievable in the event of an investigation or audit performed on behalf of Datwyler.

Safekeeping of system documents and records in a clean, dry and secure environment shall be regulated in writing with a guarantee of at least:

- 15 years after end of production of the concerned product (Automotive segment)
- 7 years after end of production of the concerned product (Health Care segment)

14 Premium freights and related costs (Automotive segment)

The provider undertakes to record all premium freights and the related costs and to present these records on request. The special freight and the related costs for his sub-contractors shall also be taken into account.

15 Ensuring supply after end of serial life

The provider undertakes to supply Datwyler with parts for at least 10 years after discontinuation of serial production. The price per piece for this purpose shall be set by mutual agreement.

Alternatively, production of a so-called 'final stock' is possible. The quantity required for this purpose shall be specified and released for production by Datwyler no later than 2 years after discontinuation of the delivered item.

16 Supplier product discontinuation

In case, the provider or his sub-contractor decides to discontinue a specific product, he shall take into account that Datwyler requires to receive a final stock that represents at least a 24 month supply, based on the average supply of the previous 12 months.

17 Right to inspect

Datwyler shall be entitled to ascertain the progress of work on any relevant order in the supplier's production facility within normal business hours, after notification.

18 Right to test

Datwyler reserves the right to verify all agreed and contractually arranged points, and may also do so on site, if necessary.

19 Advertising / reference lists

The provider, including his sub-contractors, shall treat all information as confidential and may only refer to the business relationship with Datwyler in advertising materials and reference lists with Datwyler's written consent.

20 Exclusivity / Confidentiality

The provider must treat all 'information' as confidential when an order is transmitted. The supplier shall grant total exclusivity if a prototype, development type, first sample or serial order from Datwyler exists, and/or if the development for a new product is being undertaken.

Both parties shall not disclose this agreement, technical information, and any information acquired in the process of making this agreement to others without prior written agreement of the other party.

Confidential information shall not be disclosed by the provider nor by Datwyler.

21 REACh

The provider guarantees that products ordered by Datwyler, have a REACH registration, if necessary.

22 Conflict Minerals

Datwyler supports the conflict minerals reporting performed by US stock companies and based on the Dodd Frank Act. This reporting requires providers to share information about certain minerals contained in their products and raw materials and where the raw materials were procured from.

Datwyler requires providers to support this exercise and give answers to questions and to fill in the reports in due time.

23 BSE/TSE statement (Health Care segment)

For supplied products related to the Health Care segment, a declaration concerning the protection against TSE (Transmissible Spongiform Encephalopathy) / BSE (Bovine Spongiform Encephalopathy) can be required from the supplier.

24 Ownership identification

All operating equipment (e.g. molds) which is required by the supplier to perform the production or the service and which are at his premises and in his possession but owned by Datwyler shall be clearly and permanently identified as such.

25 Supplier monitoring

The following criteria are used to assess the supplier's status:

- number of complaints
- customer notification status
- delivery performance
- number of occurrence of premium freights
- certification status
- questionnaire feedback
- audit result

This monitoring is used to focus on not sufficiently performing providers by inviting them to improve.

Depending on the severity of poor performance, a written action plan, a meeting with the management or an audit to be conducted on provider's/manufacturer's site might be required.

The supplier will be informed about his performance status on a regular frequency. On request the supplier also can receive the detailed information used for the calculation of the status.

26 Escalation procedure

Datwyler is using an escalation procedure with the goal to recognize and to counter supplier problems in an early stage. The process targets to start continuous improvement measures before severe problems cause supply interruptions from the supplier the Datwyler and/or from Datwyler to customers.

To do that, standardized containment and improvement actions have to be started with the occurrence of a number of different incidents on supplier's side. These actions are clustered in so called "escalation levels". With deviation from expected behaviour, the escalation level is increased. With improvements, positive audit results and completion of actions escalation levels can be decreased.

Defined actions start from escalation level 1 that needs to be completed in a predefined time frame. Without positive completion or unsatisfactory results of defined actions the escalation level will be increased to level 2.

With still dissatisfactory results of actions and audits the supplier will be increased to escalation level 3. Here new business will be put on hold and a monitoring process starts that can lead to the termination of the business relation with the supplier.

Esc-level	Cause	Actions
0	Single supplier complaint	• None, normal day-to-day work
	Delivery deadlines and quantities not ok	
	"A" or "B" result in supplier monitoring	
1	Repeated supplier complaints	• Request action plan from supplier
	Completion of actions beyond due date of unsatisfactory results	
	Delivery deadlines and quantities repeatedly not OK	
	"C" result in supplier monitoring	
	Serious communication issues	

	"R2" result in risk assessment	
	Special status customer notifications about risks at supplier	
2	Serious non-conformities and supplier complaints	• Request an action plan from supplier • Management meeting • Result verification of development plan (e.g. by an audit) • Verification of effectiveness of actions in defined time frames (e.g. by an audit)
	Completion of actions beyond due date of unsatisfactory results	
	Lack of willingness in problem solving	
	"D" result in supplier monitoring	
	"R1" result in risk assessment	
	Special status customer notifications about risk at supplier	
3	Repeatedly serious non-conformities and supplier complaints	• Management meeting • Definition of a development plan • New business on hold • Partial or complete loss of existing business
	Production standstill at Datwyler caused by supplier	
	Lack of willingness in problem solving	
	Special status customer notifications about risk at supplier	

27 Audit / release audit

Before the start of the serial delivery, Datwyler may conduct a release audit.

During serial delivery, at random intervals, Datwyler may repeat audits to ensure sustainable quality standards.

Datwyler, or any authority on behalf of Datwyler, shall be entitled upon providing reasonable prior notice, to perform audits/inspections of the provider's or manufacturer's quality management system, employees and facilities relevant to the manufacturing of products, during operating hours. The purpose and scope shall be stated along with the prior notice.

The provider shall assist in planning and carrying out such audits. The provider who are evaluated with poor performance, shall respond to the audit results and will follow-up on actions required within specified and agreed time frames. Datwyler reserves the right to verify the implementation and effectiveness of these measures by means of an audit or a review meeting.

The provider shall ensure that the right to audit as herein described includes sub-suppliers, where sub-supplier activities have a significant influence on the quality of the delivered products and services.

When audited by a third party, the provider shall ensure that the audit team is subject to confidentiality requirements relating to the supplier's activities being part of the business with Datwyler.

28 Internal risk assessment

Datwyler will carry out an assessment of the business risks for each serial supplier, before the start of the serial deliveries and on regular frequency.

The assessment of the risk level is based on criteria in quality, delivery performance, general and product-related criteria. If suppliers supply more than one product, the analysis for the product with highest risk potential has to be carried out.

The risk potential is divided into different classes based on the rating:

- R1 = high risk
- R2 = medium risk
- R3 = low risk

29 Other applicable documents

- DIN EN ISO 9001
- ISO 15378
- IATF 16949
- ISO 14001
- OHSAS 18001 / ISO 45001
- VDA 6.1 and the accompanying VDA volumes
- AIAG manuals
- DIN EN 10204

For all standards mentioned the latest edition is valid.

30 Roles and responsibilities

The division of responsibilities between the provider and Datwyler is described below:

1. Subcontractors	**NA**	**Datwyler responsibility**	**Contract Acceptor responsibility**
1.1. Notification of new subcontractors	☐	☐	☒
1.2. Changes regarding subcontractors	☐	☐	☒
1.3. Subcontractor approval	☐	☒	☒

2. Raw material suppliers	**NA**	**Datwyler responsibility**	**Contract Acceptor responsibility**
2.1. Approval	☐	☐	☒
2.2. Changes	☐	☐	☒

3. Raw material specifications	NA	Datwyler responsibility	Contract Acceptor responsibility
3.1. Agreed specification	☐	☐	☒
3.2. Approval of Supplier Specifications	☐	☐	☒
3.3. Approval of changes to specifications	☐	☒	☐

4. Raw Material & Packaging	NA	Datwyler responsibility	Contract Acceptor responsibility
4.1. Sampling	☐	☐	☒
4.2. Testing	☐	☐	☒
4.3. Release	☐	☐	☒

5. Specifications	NA	Datwyler responsibility	Contract Acceptor responsibility
5.1. Preparation	☐	☐	☒
5.2. Approval	☐	☒	☒

6. Batch release	NA	Datwyler responsibility	Contract Acceptor responsibility
6.1. Production quality controls	☐	☐	☒
6.2. Certificate of analysis	☐	☐	☒
6.3. Release	☐	☐	☒

7. Batch Records	NA	Datwyler responsibility	Contract Acceptor responsibility
7.1. Preparation	☐	☐	☒
7.2. Document review	☐	☐	☒
7.3. Approval	☐	☐	☒
7.4. Archiving	☐	☐	☒

8. Changes (see point 8.10 of this quality agreement)	NA	Datwyler responsibility	Contract Acceptor responsibility
8.1. Notification to Datwyler	☐	☐	☒
8.2. Approval prior to implementation	☐	☒	☐

9. Specification changes initiated by Datwyler	NA	Datwyler responsibility	Contract Acceptor responsibility
9.1. Notification to Contract Acceptor	☐	☒	☐
9.2. Approval	☐	☒	☒

10. Specification changes initiated by Contract Acceptor	NA	Datwyler responsibility	Contract Acceptor responsibility
10.1. Notification to Datwyler	☐	☐	☒
10.2. Approval	☐	☒	☒

11. Deviations	NA	Datwyler responsibility	Contract Acceptor responsibility
11.1. Initiation of Deviation Report	☐	☐	☒
11.2. Investigation	☐	☐	☒
11.3. Documentation collection	☐	☐	☒
11.4. Approval of actions	☐	☒	☒

12. Recall	NA	Datwyler responsibility	Contract Acceptor responsibility
12.1. Notification	☐	☐	☒
12.2. Investigation	☐	☐	☒
12.3. Notification of investigation results to Datwyler	☐	☐	☒
12.4. Approval of actions	☐	☒	☒

13. Complaints	NA	Datwyler responsibility	Contract Acceptor responsibility
13.1. Notification to Contract Acceptor	☐	☒	☐
13.2. Investigation	☐	☒	☒
13.3. Documentation collection	☐	☐	☒
13.4. Approval of actions	☐	☒	☒

31 Remarks

32 Attachments

Not applicable

33 Supplier Signatures

With our signature, we hereby confirm this Supplier Quality Agreement. We agree that exceptions to this agreement can only be part of a binding agreement after duly authorized agents of Datwyler countersigned the exceptions.

Provider's name:

Date and place:

Name: Title:	Name: Title:

Company stamp:

34 Datwyler Signatures

Provider's name:

Date and place:

Name: Title:	Name: Title:

This Supplier Quality Agreement supersedes previous versions and shall remain the property of Datwyler Sealing Solutions. The supplier is entitled to make copies for his own use.