

HIRSCHMANN AUTOMOTIVE

Technical Delivery Regulation

V02 - Process engineering

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This standard governs the requirements for the documentation and the general regulations for the delivery of systems.

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1. General

1.1. Area of Application

This Hirschmann Automotive GmbH factory standard specifies the delivery regulations for the documentation of machines, systems and production facilities.

1.2. Deviations

Deviations from this delivery specification which may appear necessary or appropriate to the manufacturer, require written approval from Hirschmann Automotive.

1.3. Standards/Regulations

Even if this technical delivery specification does not specify such in detail, the contractor is fully responsible for, in addition to the requirements specified in this technical delivery specification, all requirements applicable to their service arising from regulations (e.g. EC directives, regulations and other applicable laws) as well as from standards and generally accepted rules of technology.

As far as regulations, standards and technical rules are referenced in this technical delivery specification, the contractor themselves must check whether they are applicable for their work and whether other regulations, standards and rules are also to be adhered to.

If in doubt, the contractor must immediately contact the client.

In addition, the contractor shall immediately notify the client if the contractor recognises or identifies, on the basis of their knowledge, that the service to be rendered by the contractor is not suitable for the intended purpose or suited only to a limited extent.

1.4. Reject part handling

The voiding of NOK components must be guaranteed in every situation. (e.g. emergency stop actuation, start up, power failure, etc.)

NOK components can only be removed after successful voiding.

NOK component voiding cannot be disabled. No contamination of the machine may occur due to component voiding. Mixing of reject parts with good parts must be effectively avoided.

Optionally, blockage of the machine should be possible after three consecutive reject parts.

Technically related deviations are to be clarified with the responsible specialist department.

1.5. Cleanliness

Process-related contamination (cutting residues, vapours, etc) must be disposed of in a clearly defined manner (extraction, external cutting, etc.). If necessary, the machine is to be equipped so that it corresponds to the cleanliness regulations of Hirschmann Automotive GmbH. This must be clarified with Hirschmann Automotive GmbH.

1.6. Wearing parts

All wearing and spare parts must be legibly and sustainably (permanently) labelled with the spare part number.

When re-ordering spare and wearing parts, the manufacturer must guarantee that these parts 100% correspond to the original. (roundings, chamfers, polished areas,...) This must be verified by clear information on the part drawing and by a final check.

1.7. Commissioning/service

The machine manufacturer usually carries out a preliminary acceptance test. After successful preliminary acceptance, final acceptance takes place at the corresponding Hirschmann Automotive GmbH plant. Commissioning by a technician of the supplier and corresponding instruction in the factory is optional. The respective representative in the country of the recipient plant must be informed about the machine and trained.

1.8. Machine capability tests

The machine manufacturer is obliged to submit an MFU machine capability test for at least one relevant characteristic during the preliminary acceptance test. This/these characteristic(s) must be clarified/defined in advance with Hirschmann Automotive GmbH. The capability value must reach Cmk >2.0.

1.9. Lighting

Ensure sufficient lighting in the handling zone.

2. Resistance welding/compacting:

2.1. Welding head

The electrode holder must allow quick and accurately repeatable change of the electrodes (Poka Yoke). The occurrence of shunts (also from welding residues/spatters) is strictly to be avoided. A machine capability (Cmk >2.0) is to be rendered by the supplier. (e.g.: path, current and power)

2.2. Welding tool

A welding tool usually consists of welding electrodes, electrode holders, setting gauge and/or positioning gauge. The exact composition of the welding tool or any deviation from the specified components must be clarified in advance with the responsible specialist department. All single parts of the welding tool must be labelled permanently and be easily legible. A BOM and explosion drawing of the welding tool must be delivered with the documentation. A drawing of the electrodes must also be contained in the documentation.

2.3. Electrode change

All electrodes or holders are to be designed with a quick-change system. Referencing must take place automatically at the request of the installer after an electrode change. The electrode change function must be password-protected. The electrode change interval is to be ensured via a freely adjustable cycle counter. A setting gauge is to be supplied for the electrodes.

2.4. Component handling

The handling (insertion and removal of the components) should be simple and safe. Ensure precise and reproducible positioning of the welding partner/components to the electrodes. The inserted components must not be damaged in any way by clamping, gripping, inserting, removing and moving.

2.5. Access authorisation

Pages or parameters can be correspondingly enabled or locked through the different user levels. The user levels can be freely configured in the highest level. At least four user levels must be provided. Automatic logout must occur after a definable time.

2.6. Monitoring

The following parameters must be monitored, recorded and stored during welding.

- Weld time (t)
- Force (F)
- Current strength (I)
- Voltage (U)
- Penetration (resolution at least 1 µm)
- Component recognition

3. Crimping

3.1. Press

The dimension of the crimp press is to be designed according to the contacts and the crimp tool used. The press stroke is 40 mm as standard. The closing height and the guide play must be adjustable. The reproducibility of the lower deadpoint (135.78 mm) is proven by the manufacturer's machine capability test (MFU). The use of conventional quick-change tools from different manufacturers must be possible.

3.2. Crimp force assurance / other monitoring

The crimping devices, which include both fully automatic wire processing machines and semiautomatic crimping machines, must be equipped with a device for permanent automatic monitoring of the crimp quality. Crimping devices must be equipped so that a uniformly high crimp quality is ensured and defective parts are reliably sorted out.

Crimp monitoring systems are preferably to be integrated into the machine controller or alternatively to be fixed to the machine controller. Deactivation of the crimp monitoring system from Hirschmann Automotive's side is fundamentally not possible. (e.g. safeguarding through special user level) in production mode the monitoring is completely locked. The lock is preferably secured by a keyswitch or alternatively by a configurable user level. Separate teaching in of different wires (e.g. wire colours) in a sheathed cable must be possible.

For semi or fully automatic crimping machines with automatic socket or pin carrier fitting, an optical check is to be arranged of the crimp quality. (Camera)

Furthermore, an automatic push-pull or comparable check is obligatory to be implemented.

The types of monitoring systems which are used as well as the areas to be checked should be coordinated with the responsible specialist department.

The cyclical calibration must be marked on the crimp monitoring system with an appropriate sticker. Connection to an MES system (standard protocol OPC-UA) is provided.

3.3. Press clamping plate for crimp tools

The use of conventional quick-change tools (longitudinal transport and lateral transport) from different manufacturers must be possible (e.g.: Schäfer, Hanke, Schleuniger, TE, MECAL, JST, etc.). The press clamping plate must be designed so that all tools can be securely clamped and a quick and accurately repeatable change of tools is possible.

3.4. Contact roll holder / reel / feed contacts

The contact roll holder as well as the reel should be designed for all conventional contact rolls (up to diameter 800 mm). The use of back-feed contacts must also be possible. The feeding area must be designed in such a way that the contacts cannot get caught, bent, jammed, etc.

3.5. Paper winder / alternative feed winding aid

The paper winder must be designed for all conventional contact rolls (up to diameter 800 mm). The tension-free feeding of the contacts to the tool must be ensured by sag control or comparable systems. Preference is given to systems with which scraping of the contact surface can be ruled out. Precise alignment of the paper winder to the reel must be possible. Optionally contact end monitoring should be offered.

3.6. Contact strip cutter

The machine must be fitted with a contact strip cutter, which safely cuts the contact strips outside the tool and disposes of them in a container provided for the purpose, as unmixed as possible. The definition of the cutting time must be programmable via the control system. (depending on tool / feed type). Feeding to the contact strip cutter must be designed that the contact strips can be fed to the cutting area easily and without effect on the crimp quality. The contact strip cutter should be suitable for all contact types, if possible. (e.g. adjustment option)

Contamination of the machine by cutting residue is not allowed.

3.7. Integrated stripping unit / cable handling

When using an integrated stripping unit, easy feeding and precise positioning of the wire to knife block must be ensured, and as a result to the crimp zone.

Gripper, introduction screens and knife are to be adjusted to the wire to be processed. Optional use of different knife types must be possible. The knife must be able to be set precisely and with repeatable accuracy. The stripping unit must be fitted with a knife recirculation (wayback), which can be set and also deactivated according to wire type. Furthermore, quality assurance devices should optionally be available such as a continuous cut-in monitoring, optical monitoring of the stripping quality or similar systems.

Damage to the wire insulation by the gripper and the notching, scraping or cutting of strands/wires during the stripping process is not permitted.

With semi-automatic machines, the use of a zero-cut must be possible. The length of this zero-cut must be adjustable.

If parts have to be changed when changing over to another wire, a different cross-section or an alternative stripping length, they must be combined in a "stripping set". Changing of change parts must be easy and with repeatable accuracy.

The exact composition of the stripping set must be clarified in advance with the responsible specialist department. All parts contained in the set must be clearly and legibly labelled. A BOM and explosion drawing of the stripping set must be delivered with the documentation.

Cutting waste and stripping residue must be cleanly and safely removed /vacuumed away. The use of laser stripping devices is also possible. We kindly ask you to contact the responsible specialist in this regard.

3.8. ELA / seal assembly

A seamless presence query must be carried out when the single conductor seals are fed in. Seal positioning on the wire must be possible before or after the stripping process. Seal application sets must be provided in suitable boxes and be uniquely able to be assigned to the respective seal. All the parts contained in the application set must be clearly and legibly labelled. A BOM and explosion drawing of the application set must be delivered with the documentation.

Changing of seal application sets must be easy, quick and reproducible.

3.9. Forming fluid container (contact strip wetting)

It must be possible to optimally position or adjust the container for the forming fluid to suit the specific contact.

Wetting of the outer wire crimp zone with forming fluid must be guaranteed throughout. Refilling of the forming fluid must be easy.

We kindly ask you to contact the responsible specialist regarding the design and the method.

3.10. Reject part handling

Reject parts detected by the crimp monitoring must be safely evaluated by the machine. The evaluation takes place by separating the wire as soon as possible behind the crimp contact. A separate knife must be used for the evaluation. Parallel use of this knife as stripping knife is not allowed. An optional connection is to be provided for a reject parts container. If NOK components are detected, the status must be permanently stored until reset by the reject part evaluator or stored in the reject parts container. (also in case of power loss, emergency stop, etc.) cutting residues, which occur during the evaluation of reject parts, must be disposed of in waste containers. Contamination of the machine by cutting residue is not allowed.

Deactivation of the reject part evaluation is not possible from Hirschmann Automotive GmbH's side.

3.11. Special applications

Special applications such as sliding table machines, step cut, special taping of contacts etc, are always to be clarified with the persons responsible for the process.

4. Fully automatic cutting and stripping

4.1. Cable feed

In order to ensure even and gentle feeding, a cable feeding system with a storage facility must be provided which is coordinated with the cable bundle. Damage such as friction marks on the wire are not permitted. A positioning unit is to be integrated to straighten the wire. Splice, presence and cable end monitoring must be available and monitored via the machine controller. Depending on the application, a special feeding device may be required. Clarify the special requirements with the persons responsible for the process.

4.2. Cable feed and length measuring system

It must be demonstrated that the length measuring system achieves the required tolerances and an repeatability (Cmk \ge 2.0). The relevant tolerances are to be clarified with the persons responsible for the process. Slip monitoring must be provided. Damage from the length measurement system or the cable feed is not permitted.

The machines must be constructed so that the optimum feed system can be used for the wire types to be processed. (feed roller, belt feed, different belt coatings, etc.)

4.3. Stripping

The knife type and the diameter are to be coordinated according to the cable to be processed and the insulation materials used. Select the knives so that as high a service life as possible can be achieved. Damage to the core insulation, the wire or the cable sheath is to be avoided. A knife return (way-back function) is to be implemented as standard. A zero-cut function must be available. The cutting edge must run at right angles to the wire axis. Continuous cut-in monitoring and a slit function are to be optionally offered.

The tolerances for cutting to length and stripping specified in the product drawing must be adhered to reliably in the process (Cpk \geq 1.67).

4.4. Component handling

The processed wires are to be placed longitudinally in an intermediate trough and, depending on the number of pieces, in the removal trough. The removal trough must be accessible from outside during operation to enable the continuous removal of the wire bundle. The length of the storage space is to be designed according to the minimum and maximum length of the products to be processed.

4.5. Control system

Depending on the products to be processed, a printer interface is also to be offered for the wire printer. The setting parameters must be able to be read in and read out both locally as well as on a network drive. A log file is to be kept on the users logged in/out, parameter changes and error messages.

4.6. Twist strand ends

The strand end twisting module must be integrated into the machine controller and ensure gentle, precise and accurately repeatable twisting of the strand ends. The possible twist range must comply with the requirements of Hirschmann Automotive GmbH. This is to be clarified with those responsible for the process.

4.7. Tinning/flux

Flux and tin modules must be suitable for lead-free tinning of strand ends. The module must be integrated into the machine controller and enable a reliable process flux/tinning. For optimal tinning adapted to the respective product, an adjustable, constant tin flow must be guaranteed. The tin nozzle must be adjusted as well as possible to the product. The tin station must be constructed so that slag formation can be kept to a minimum. Cleaning of the tin nozzle and the pump channel must be simple and done without tools, if possible. The flux station must be constructed so that reliable wetting of the strand ends can be ensured. Furthermore, contamination by the flux should be avoided as far as possible. The accessibility of the flux container must allow easy refilling.

4.8. Marking

The printer and the printing principle are to be coordinated with the product to be processed along with Hirschmann Automotive. The printer will communicate with the cutting machine over an electrical interface. If a medium is required for the print technology, monitoring is provided. Optionally, the printing process and the printed image (data matrix, alpha-numeric string, barcode, logos, etc.) can be checked by appropriate measures and it can be ensured that the print process has been executed correctly on the wire. Non or misprinted parts / wires must be automatically and securely discharged as reject parts. Any danger of confusion with good parts is to be avoided.

4.9. Twisting of single wires (on one cutting machine)

During twisting, the wires as well as the components may not be damaged or subjected to strong pulling. Pitch errors are not allowed. Clamping directly on a possibly available crimp connection is not permitted. All process parameters (number of rotations, speeds, tensile forces, etc.) are to be programmed via the control system. Calculation of the cutting length must take place automatically via the programme. Special, product-specific topics must be clarified with the persons responsible for the process.

4.10. Fitting (in combination with a cutting machine)

The components to be fitted (contact carrier, connector, etc.) must be supplied in the correct position, free of malfunctions and damage. The wires with the corresponding contacts must also be mounted in the correct position, free of malfunctions and damage. An automatic push-pull or comparable check is obligatory. The autonomous time for feeding is basically to be defined as at least one hour and must be clarified with Hirschmann Automotive GmbH in any case. Part identification is to be optionally offered to exclude mixing up the parts. The feed must be covered over the whole section to avoid contamination.

4.11. Shielding turnover/cutting

The shielding and the insulation which lies below it may not be damaged. It must also be ensured that all parts of the shielding are turned over cleanly and homogeneously. When cutting the shielding, all parts of the shielding must be separated cleanly. Shielding residue must fall into a separate and closed container so that nothing can get into production.

5. Semi-automatic seal assembly

5.1. Feeding/assembly

Damage or twisting of the seals due to the feed and assembly must be effectively prevented. The manufacturer must prove this by means of assembly tests (preliminary acceptance). The assembly process must be accurately repeatable and safe. In general, damage to the components involved is not permitted.

5.2. Monitoring

The following parameters must be monitored, recorded and stored during seal assembly:

- No double fitting
- No empty fitting
- Length of the seal
- Colour of the seal

5.3. Access authorisation

Pages or parameters can be correspondingly enabled or locked through the different user levels. The user levels can be freely configured in the highest level. At least four user levels must be provided. An automatic logout must occur after a definable time.

5.4. Reject part handling

In general: The machine is not released for the next fitting cycle until NOK components are placed in the reject part container and this is also registered and recorded by the control system (reject part counter). The storage of NOK (not OK) components must be guaranteed in every situation. (e.g. emergency stop actuation, power failure, etc.)

- Seals which are detected as NOK components must be automatically stored in a closed seal discharge box. The seal discharge box is monitored for overfilling.
- Connector components detected as NOK must be stored in a separate and closed box (defined by Hirschmann Automotive GmbH).
- The storage of NOK cable sets takes place in a separate reject parts box, which is connected to the machine control system.

5.5. Operation

To support the operating personnel, a pilot lamp (e.g. ON switch) should flash green for a correctly fitted component (status: ready). When the machine is not ready or in the event of a fault (status: machine not ready) this is permanently lit red.

6. Taping

6.1. Taping

Automatic systems for selective or linear taping must enable efficient, high-quality and process-safe working. A machine capability (Cmk) of \geq 2.0 is to be demonstrated via the length measurement system. The machines must be suitable for use of commercially available rolls of adhesive tape with a core diameter of 3" and optionally also for 1.5". Easy unwinding of the adhesive tape must be ensured by an unwinding aid. No lateral/longitudinal forces may occur during the taping process which could cause damage to the cable set. The machines must be designed in such a way that they can be easily, quickly and reproducibly converted as required. Identical machine types must have an identical machine zero point. This should ensure that uniform programmes can be used for products on these machines.

6.2. Clamping cable sets

To be able to ensure high-quality taping, cable sets must be clamped between the holders. Checking the clamping force must be easy and reproducible. The devices and measuring equipment required for this should be optionally offered. From a technical point of view, permanent force monitoring is to be favoured for linear taping.

6.3. Component holder

The component holder is specially adapted to the product to be taped and has its own BOM. The holder must allow a taping in line with the drawing.

The holder must be designed so that connectors, cable ends, etc. can be inserted simply, positioned correctly and reproducibly. Damage to the cable sets to be taped from sharp edges, tensile strain, clamping jaws, lateral forces and such like is not allowed. The holder materials are to be chosen so that wear can be virtually excluded. All the parts of the holder must be permanently, legibly labelled and clearly assignable.

6.4. General control system

A list of the factory default set parameters (machine control system) is to be enclosed, as well as a backup delivered on a corresponding medium. Access options (remote maintenance) to the machine control system must be provided via hardware (Ethernet RJ-45) as well as software to enable corresponding support by Hirschmann specialists or the suppliers. Connection to an MES system (standard protocol OPC-UA) is provided. An interface for an NOK box is compulsory.

6.5. Access authorisation

Pages or parameters can be correspondingly enabled or locked through the different user levels. The user levels can be freely configured in the highest level. At least four user levels must be provided. An automatic logout must occur after a definable time.

6.6. Reject part detection/handling

When the end of the belt is reached, in case of overload or other malfunctions (excessive force), the machine switches to malfunction. This state is unmistakeably indicated to the employee through a red lamp and the machine is locked. This lock can only be lifted by disposing of the cable set in the nok box.

7. Laser

7.1. Construction of laser cell

The laser cell must be constructed in such a way that there is no risk of injury to the operator or to maintenance personnel. If necessary, the laser unit must be encapsulated.

The design of the laser chamber is to be structured so that the safety circuit does not switch with each cycle. If this is not possible, Hirschmann Automotive GmbH must be informed immediately to work out a solution.

The safety switch (maintenance flaps) must be screwed in a fixed position and the position may not be adjusted. The gap between actuator and sensor is to be chosen so that it lies at the end of the switching hysteresis.

All feeders or cleaning covers must be protected against laser scatter radiation by labyrinth transitions. The covering of the labyrinths must be higher than the switching hysteresis of the safety switch. Likewise, all separating planes (e.g. movable to fixed components) must be provided with a labyrinth seal in the beam direction.

At no time may laser scatter radiation be emitted from the laser nest.

Performance Level D must be observed for all safety-related models with regard to laser safety. This must be documented in the instructions.

The laser class achieved must be visible on the machine. If Class 1 is not achieved, this is to be immediately clarified with the laser representative of Hirschmann Automotive GmbH and must be released separately.

7.2. Scanner / laser head

The laser processing head (e.g. scanner) must be screwed on in a stable and fixed position. During processing, there must not be any change in position due to shocks that could have a negative effect on the result or the laser.

The laser's focus point must be at processing height, the real working distance must be determined with an examination.

When using a Cossjet under the optical laser protection glass, the flow must be adjustable. Furthermore, a 5 μ m air filter is to be used. The lag time after a system stop/standstill must be adjustable.

The laser head is to be protected against contamination in the laser protection booth with a protective sleeve (e.g. textile).

7.3. Components with durability

If there are components (e.g. circuit boards, relays, SIK TruMark) which have limited durability, a counter is to be integrated for each one which has a freely selectable password and can be reset, which counts down and outputs an early warning message. Furthermore, Hirschmann Automotive GmbH must be informed immediately.

7.4. Cleaning

There must be an access hatch which is easy to dismantle, so that the operator can clean the protective glass on the laser outlet opening and on the inscription head as well as the laser chamber. There must be a job-related instruction in the instruction manual on how to clean the protective glass on the laser outlet opening.

All covers for the laser area which can be dismantled, which are used for maintenance (e.g. cleaning lens) must be constructed so that they can only be mounted in one position (Poka Yoke). Under no circumstances may the safety switch be actuated by a wrong position of the cover. All attachments to the laser chamber (e.g. air vents) must be screwed on from inside; no screws may be visible from outside. All screws of the laser chamber which do not have to be opened periodically for maintenance work (maintenance flaps) are to be sealed with sealing wax.

7.5. Laser processing

The laser used must be able to perform a power measurement in order to readjust, if necessary.

If a pilot laser can possibly be used for setting up, it is to be clarified with the Metal Process Engineering department whether this should also be ordered.

If it is possible to implement an observation camera in the beam path with crosshair generator in order to adjust and observe the process, this must be coordinated with the Metal Process Engineering department to determine whether this is also ordered.

A machine capability of the laser performance is also to be delivered.

If no part was inserted in a nest or it remains empty due to an nOK part, the laser may not process the empty nest

It may not be possible in series production that a part can be laid in the focussing area (between lens and part to be inscribed).

The laser nest must be constructed so that a build up of smoke is not possible, especially in the focussing area.

There must be a monitoring system that detects whether each part has fallen out of/been removed from the laser nest after processing.

7.6. Laser inscribing

The Z position of the laser head must be adjustable +/-20 mm in Z direction. The centre is the real focus point of the head. After setting up, the head must be fixed in a positive lock; there must be no adjustment of the Z axis.

The selected inscribing laser must be discussed with Hirschmann Automotive GmbH and released by them.

When reading codes or plain text, it must be clarified in what quality and with what kind of lighting (e.g. according to ISO) this must be carried out.

7.7. Laser welding

The Z position of the laser head must be adjustable and be able to be clamped +/ -50 mm in the beam direction with a screw/ threaded spindle with a pitch of 1 mm. The centre is the real focus point of the head.

After setting up, the head must be fixed in a positive lock; there must be no adjustment of the Z axis.

It must be possible to measure the laser performance with a load cell after exiting of the laser head.

7.8. Laser extraction

The extraction filter must be designed so that the exhaust air can be delivered back into the room. To avoid fine dust pollution, the laser station extraction must be equipped with at least one HEPA filter unit of class H13, activated carbon filter, or in accordance with national laws.

The status of the extraction filter unit is to be monitored and reported with a message when it's full.

A written document from the extraction manufacturer regarding the suitability of the filters used for the laser process must be provided. This must be specified with the appropriate documentation in the instructions

The state of the extraction must be monitored (extraction on/off). Laser processing should not be possible without extraction.

The extraction lag time must be adjustable via the control system.

The worker must have the option of starting the extraction on the user interface, the length of the switch-on time must be freely adjustable. This is used to clean the laser chamber in manual mode.

The suction effect of the extraction may not affect the position of the part during processing.

In case of possible flying sparks during laser welding, the extraction must be protected against damage (fire) accordingly.

The type and size of extraction must correspond to the incident amount of dirt. A filter cartridge must withstand at least 3 months of series operation. If this is not possible, Hirschmann Automotive GmbH must be informed immediately to work out a solution.

Opaque suction hoses must be used. They must be clamped with raw clamps and secured against unintentional removal with a screwed-through screw. The suction hose may not be mounted in the laser beam direction.

The negative pressure of the suction in the laser chamber must be monitored at the transition from the laser chamber to the suction hose.

The suction device should be positioned as close as possible to the laser chamber.

7.9. Damage

The high energy radiation during welding may not cause damage to the component or the tool. All component areas which are not required for welding are to be covered with suitable materials.

7.10. Control system

A list of the parameters set is to be enclosed, as well as a backup delivered on a corresponding medium.

It must be possible to back up the data of all parameters and programmes, and if required reading this back in.

Access to the laser programming level must be protected with a password or keyswitch.

With lasers, it must be possible to use Industry 4.0 (OPC-UA interface).

It must be possible to connect the laser to a BDE system (Traceability).

It must be possible to remotely access the laser control system.

7.11. General

A detailed breakdown of the spare and wearing parts including costs, service life and the documentation must be included.

It must also be specified how long the spare parts supply is guaranteed for.

If protective/process gas is used, this must be discussed and approved in advance with the Metal Process Engineering Department.

7.12. Laser safety

Laser safety is specified in the Technical Delivery Regulation S01.