SUPPLIER NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ CONTACT DETAILS\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This agreement outlines our requirements in relation to the purchasing of materials and services in accordance with AS 9100 Rev D/ISO 13485:2016 Quality Management System requirements.

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| **Requirement** | **Requirements** | **Additional Notes** |
| Name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant data. | Exact CNC NI Ltd. will supply copies of all applicable documentation and specifications applicable to the product or service requested. | Supplier to control all documentation and ensure confidentiality as notified.  Supplier to ensure they are holding the correct issue and dispose of all OBSOLETE documentation in a secure manner. |
| Approval of Product | All products produced on behalf of Exact CNC NI Ltd. must be inspected and tested against our specified performance criteria. | Evidence of inspection and testing and final approval must be forwarded with each batch, as requested in Purchase Orders.  Supplier will be notified of any statistical techniques (e.g. sampling plans) to be used in conjunction with product inspection and test. |
| Non-Conforming product | Supplier must notify Exact CNC NI Ltd. of any significant non conformance which affects the product. | Concessions can only be granted with main customer approval (where applicable) and must be signed by Exact CNC NI Ltd. and the Supplier.  Copy of concession to be held by Exact CNC NI Ltd. and Supplier. |
| Corrective Action | Supplier must issue Exact CNC NI Ltd with details of corrective action taken on problems notifies to the supplier. | Exact CNC NI will issue supplier with details of non-conformances using a Supplier Corrective Action Report (SCAR Form) |
| Approval of procedures | Any procedures requiring approval will be notified to the Supplier in PO. | Two copies of procedures must be forwarded to Exact CNC NI Ltd. for approval.  After approval one signed copy will be returned to Supplier. |
| Approval of processes | Any processes requiring approval will be notified to Supplier in our PO. Arrangements for approval will be detailed.  NOTE: Supplier must use customer-approved special process sources when notified by Exact CNC NI Ltd.  Details of source/s will be forwarded to Supplier as part of our purchasing process. | Exact CNC NI Ltd. will visit Supplier to approve processes, as appropriate.  NOTE: It is a requirement that the Supplier notifies Exact CNC NI Ltd. of any process changes which may affect the product/service ordered by Exact CNC NI Ltd. |
| Changes to purchased product | Supplier must notify Exact CNC NI Ltd. of any planned changes to purchased product that can affect the ability of the product to meet specified requirements.  Change can only proceed when approved by Exact CNC NI Ltd Precision Ltd. | Exact CNC NI Ltd. will evaluate the proposed change and its effect on the purchased product.  Exact CMC NI Ltd. will notify the supplier in writing, that the change can proceed.  Where the supplier has issued an Engineering Change Note/Request, if change is agreed it will be signed and returned to supplier so that change to product can proceed.  A copy of the ECN/ECR shall be maintained by supplier and Exact CNC NI Ltd. |
| Risks | Exact CNC NI Ltd. expects its suppliers to identify risks to supply and put in place measures to eliminate or minimise risk. | Exact CNC NI Ltd. will inform supplier of any specific risk assessments required in relation to product or service being supplied in our Purchase Order. |
| Traceability | Batch No/Lot No. may be required to facilitate traceability in event of a product recall. | If traceability is a requirement for an order Exact CNC NI Ltd. will notify the supplier of the need to allocate a batch or Lot number, to goods/materials supplied. |
| Approval of equipment | Any equipment requiring approval will be notified to Supplier in PO.  Arrangements for approval will be detailed. | Exact CNC NI Ltd. will notify Supplier of approval. |
| Calibration | All measuring and test equipment used must be in a current state of calibration | If Exact CNC NI Ltd supplies any measuring or test equipment its calibration will be controlled by Exact CNC NI Ltd. |
| Certificate of Conformance (C of C), Material/ Certificates | Requirement for C of C and relevant material certificate will be stated in PO | C of C must be signed by Supplier’s Quality representative and state that products/materials have been inspected and or tested and meet Exact CNC NI Ltd. and/or customer specification.  Material Certs must be provided when requested on a purchase Order. |
| Qualifications of personnel | Any specific Qualification relating to personnel will be stated in PO. | Qualification of personnel will only apply when specified by Exact CNC NI Ltd. Customer. |
| Record Control | All records created by and /or retained by Suppliers in relation to our product must be controlled. | All records created by Suppliers must be controlled and held for at least 11 years. Records must be available to our customers and Regulatory Authorities on request.  If a longer period is required to accommodate the lifetime of a medical device the extended period will be notified on our Purchase Order |
| Quality Management System requirements | Any specific requirements relating to Quality Management System (QMS) will be stated in PO. | It is preferred for the Supplier to hold AS 9100 Rev D/ISO 13485:2016/ISO 9001:2015 or equivalent certification for its QMS. |
| Performance Monitoring and measuring | Exact CNC NI measures supplier performance in relation to Quality/Delivery/Cost and Dealing with problems. | The supplier will be notified when their performance falls below expected performance and will be required to issue Exact CNC NI Ltd. with an improvement plan on actions taken to improve performance to an acceptable level. |
| Counterfeit Parts/Materials | Exact CNC NI Ltd. requires its suppliers to have a process in place to prevent the use of counterfeit parts or materials or supply of same to Exact CNC NI Ltd. | A copy of Counterfeit Policy must be supplied .to Exact CNC NI Ltd. |
| Human Rights | Exact CNC NI Ltd. expects its suppliers to have in place Human Rights policies and practice these in their company operations, that combat modern slavery and trafficking. These policies should comply with the standards set out in HRF021- Human Rights and HRF038- Anti-Slavery and Human Trafficking Policy. | Copies of policies should be forwarded to Exact CNC NI Ltd. when requested in a Purchase Order or Supplier Questionnaire. |
| Ethical Behaviour | Exact CNC NI Ltd. expects its suppliers to have in place ethical policies and practice these in their company operations.  It is also expected that these policies are flowed down to their suppliers/sub-contractors. | To provide evidence, copies of policies can be forwarded to Exact CNC NI Ltd. when requested in a Purchase Order or Supplier Questionnaire. |
| Contribution to product safety | It is expected that all relevant employees are made aware of their contribution to product safety and have been provided with Foreign Object Debris (FOD) training. | Supplier will be made aware of any safety critical items on the Purchase Order or on drawing or specification supplied. |
| Regulatory requirements | Any applicable Regulatory Requirement stated on an Exact CNC NI Ltd. purchase order must be complied with, by the supplier. | Exact CNC NI Ltd Ltd. will notify supplier on the purchase order of any regulatory requirements, applicable to an order. |
| Right of access | Exact CNC NI Ltd., its customer or Regulatory Authority reserve the right to visit their Suppliers and 2nd tier Suppliers involved in the order to carry out an audit or investigate a complaint and to visit applicable area or applicable documentation at any level of supply chain. | Arrangements for visit will be agreed with Supplier by Exact CNC NI Ltd. |

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| I am in agreement with above purchasing requirements which will be applied to all Exact CNC NI Ltd. orders.  Signed by Supplier:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signed by Exact CNC NI Ltd. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |