

TECHNICAL APPLICATION GUIDE

MKTECH INDUSTRY SDN BHD

PRECISION SURFACE FINISHING MEDICAL COMPONENTS

Protect geometry, texture and cleanliness

Zone-by-zone finishing, abrasive progression, measurement and change control. Includes a worked coupon trial and two printable worksheets.

For medical manufacturing engineers, process owners, technicians and quality teams.

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01 / PURPOSE AND NAVIGATION

Specify the surface by function

Build the finishing route from the drawing, the surface's function and the evidence required for acceptance. A component may have different texture, form and cleaning requirements in adjacent zones.

Map the features

Locate functional surfaces, protected edges and areas with defined texture or treatment.

Control each stage

Agree the tool, support and endpoint. Prevent abrasive and compound carryover.

Verify and record

Check the required geometry, texture and cleanliness by their specified methods.

Find the right section

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Set the technical boundary

The device manufacturer sets the requirements

Work to the applicable drawing, approved process and quality management system. The manufacturer determines device-specific cleanliness, biological evaluation, validation and release requirements. Apply the contract and applicable market requirements for the actual work. [1-3, 6-9]

QMS = quality management system. Ra = arithmetic mean profile roughness. Lay = predominant direction of the surface pattern. SDS = safety data sheet.

02 / DRAWING AND SURFACE ZONES

Map the features before finishing

Locate each finish requirement against a drawing datum. Identify the initial material condition, permitted removal and areas that must retain their geometry, texture or treatment.

EXAMPLE SURFACE	DEFINE THE REQUIREMENT	CHECK BEFORE RELEASE
Mating, sealing or bearing surface	Specify zone, size or form, texture parameter and lay where required.	Geometry at designated points and the specified surface measurement.
Edges, holes and threads	Define the permitted edge condition and protected fits, features and marking.	Specified burr and edge checks, dimensions and access.
Textured or treated zone	Identify the boundary and the treatment or texture to preserve, such as a specified porous region.	Integrity of the protected zone and the required treatment or texture evidence.
Other visual surfaces	Use the specified reference sample, visual criteria or measured finish for that zone.	Condition recorded using the specified lighting, orientation or inspection method.

Example of a zone map for a trial coupon

ILLUSTRATIVE PLAN VIEW / NO DIMENSIONAL SCALE



Use the approved datum, limits and zone boundaries for the actual job.

Give every protected feature its own check

In this sketch, A and B identify checks in the finishing zone. The protected shoulder needs its own location, method and limit. Resolve unclear boundaries with engineering before starting.

03 / PROCESS ENGINEERING

Set a handover for every stage

Define what each stage must deliver to the next. Put required checks and records in the traveller or approved work instruction, including the order of cleaning, treatment and inspection. [2, 3, 6]

STAGE	CONTROL THE OPERATION	RECORD BEFORE PROCEEDING
1. Confirm material and drawing	Verify part revision, material and starting surface. Mark finishing and protected zones and locate checks.	Part and lot IDs, work instruction revision and as-found condition.
2. Correct permitted material	Use the approved tool and fixture. Verify critical form and remaining allowance at the required checkpoint.	Tool and media identity, critical readings and any deviation.
3. Refine the scratch pattern	Follow the approved stage sequence. Inspect the result and use the specified cleaning between stages.	Stage completion, media traceability and inspection or exception.
4. Establish final surface	Use the required finish and lay. Apply any specified treatment at its prescribed point.	Required finish results, treatment records and batch references.
5. Clean and protect	Apply the approved cleaning and handling route. Prevent recontamination in transfer and storage.	Cleaning batch or cycle record, specified tests and handling status.
6. Verify and disposition	Perform remaining checks in the approved sequence. Reconcile each lot and route exceptions to quality.	Inspection and release evidence, or controlled hold and disposition.

Identify the surface state at each check

Record whether the result was measured before or after the specified surface treatment and final cleaning. If either operation changes the measured state, follow the inspection sequence in the control plan.

Define the action for a failed gate

Protect the part and retain the as-found evidence. Route any further removal, cleaning or other rework through the approved disposition before continuing.

04 / TOOLING AND MEDIA

Match the abrasive to the surface

Choose the media, backing, fixture and working envelope together. Confirm the exact material grade, allowed removal, protected zones and contamination controls. [6, 9, 10]

APPLICATION	SELECTION FACTORS	EVIDENCE TO CAPTURE
Local burr or feature correction	Evaluate an approved point, burr or other specified tool for access and control near the feature.	Tool and holder, controlled setup, location and verified edge or remaining form.
Defined scratch refinement	Select the approved belt, sheet or film and its support. Check contact width and repeatability.	Product code, grade system, backing, stage and result at the required inspection point.
Polish where specified	Control pad, wheel or compound identity and its compatibility with the approved cleaning route.	Media and compound traceability, finish result and cleaning handover.
Directional or satin finish	Use the specified media and support with the required direction and visual reference.	Lay, texture where required, reference match and boundaries.

Record the material-specific controls

Stainless steel

Confirm grade and treatment condition. Apply required segregation and transfer controls.

Titanium or other alloys

Check the permitted tool and heat controls. Assess dust and residue for the actual task.

Treated or porous surfaces

Protect the required surface. Use the approved route for areas with restricted contact.

Record full product and support codes. Variations in grain, binder, backing and compound can change the finish and the residues sent to cleaning. [6, 8-10]

Review the proposed system through the downstream steps

Confirm how any change in tool, support or compound affects the specified finish and the qualified cleaning or surface-treatment route. Record that assessment with the trial.

05 / SCRATCH PROGRESSION AND FORM

Protect geometry during finishing

Start from the required surface and work backward to the earliest permitted operation. Define what must be removed at each stage and what must be preserved. [4, 5]

01 **Record the original surface and the inspection points**
Identify the machining marks, defect or burr and its location. Record the baseline geometry and available removal allowance at the locations called up in the plan.

02 **Control support and contact**
Use the specified support, fixture and contact method. Protect edges and narrow land areas from unintended contact or rounding.

03 **Inspect before moving finer**
Check that the prior-stage pattern has cleared to the required condition. Use the specified lighting, magnification or measurement. Keep the required direction of lay.

04 **Clean the part and tooling between stages**
Follow the specified cleaning and handling route. Use identified supports and abrasives to prevent coarse particles reaching a finer stage.

05 **Review the remaining allowance before correction**
If a mark remains near the removal limit, preserve the evidence and obtain disposition. Include any previous rework in the assessment.

Record conditions as the tool wears

Check tool condition at the defined interval. If heat, smearing, chatter or a different scratch pattern appears, hold the affected work and review the tool, support and operating record.

A surface can meet texture and miss geometry

Verify the protected edge, form or fit separately from the appearance or roughness check. Record the actual results against each criterion.

06 / CLEANLINESS AND TREATMENT

Control residues during finishing

Finishing can leave abrasive grains, metal particles, fluid or compound residues. The device manufacturer's risk assessment and process specifications define the controls and verification. [6-9]

STAGE OR RISK	CONTROL TO DEFINE	EVIDENCE TO KEEP
Between abrasive stages	Use the specified cleaning method and segregated tools, supports and storage where required.	Stage, cleaning or transfer method, equipment and affected lot.
Hard-to-clean features	Consider holes, narrow gaps, porous regions and other features that can retain residue. Use the device-specific procedure for extraction or inspection where applicable.	Locations, method, sampling rationale and results for the required contaminants.
Surface treatment where specified	Follow the authorised sequence for any passivation, electropolishing or other treatment. Verify applicable effects on geometry, finish and subsequent cleaning.	Process and batch references, status and required post-treatment checks.
Final clean and protected transfer	Use the approved cleaning, drying, handling and storage controls. Protect the clean state through the next step.	Cleaning and inspection records, packaging or transfer status and deviations.

Use the cleanliness method specified for the device

Visible residues, particles and chemical residues may require different checks. Record the applicable method and limits. Control the sources of contamination that the approved cleaning process was qualified to address. [6, 7]

Keep separate evidence for separate requirements

Surface finish, manufacturing cleanliness, biological safety and sterility each have their own device-specific evidence. The device manufacturer determines what applies. [1, 2, 6-9]

07 / MEASUREMENT AND VERIFICATION

Verify the specified surface

For each feature, define the method, measurement location, timing, units and decision rule. Use a calibrated or verified measurement system as required by the control plan. [2, 4, 5]

CHARACTERISTIC	HOW TO ESTABLISH THE RESULT	WHAT TO RECORD
Visual finish and burrs	Use the specified lighting, magnification, reference or image criteria for the actual zone.	Feature ID, orientation, defect location, image or sample reference and disposition.
Size, edge or form	Use the specified dimensional or optical method at the defined datum and location.	Instrument, fixture, measured values, units and limit source.
Surface texture and lay	Use the specified parameter, method and orientation. Profile and areal measurements use different definitions and measurement conditions.	Parameter, units, direction, filter or cutoff, evaluation length or area, and individual results.
Cleanliness and treatment	Apply the approved test or review the process record at the specified stage. Use a suitable method for the residue or treatment requirement.	Report, method, acceptance source, lot link and status.

Resolve measurement limitations before deciding

A stylus may have limited access on short or curved surfaces. If the approved method cannot measure the required area, route the issue to metrology and quality for an approved approach. Review repeatability and measurement uncertainty where they affect the decision. [4, 5]

Texture

Compare readings using the specified parameter, location and settings.

Geometry

Use the datum and method required for the feature, including the edge or profile.

08 / TROUBLESHOOTING AND HOLDS

Investigate the failure by zone

Identify the affected feature, last accepted check, lot and operation. Retain the evidence and use the quality procedure for holds, investigation and restart.

OBSERVED CONDITION	REVIEW POSSIBLE CONTRIBUTORS	IMMEDIATE ACTION
Isolated scratch after polish	Earlier-stage damage, trapped coarse grains, support damage or contact during transfer.	Record location and pattern. Review remaining allowance and permitted correction before rework.
Radius or edge out of tolerance	Excessive compliance, fixture or contact change, tool path, or cumulative removal.	Hold the part. Verify the feature with the specified method and obtain disposition.
Texture reading fails with acceptable appearance	Wrong stage or lay, worn media, measurement location, filter or instrument setup.	Preserve the reading. Verify the inspection setup and follow the approved decision rule.
Visible residue or particle result fails	Media, compound, handling or fixture transfer. Consider retained residue in restricted features.	Hold affected work. Review the cleaning and handling record and approved verification plan.
Heat marks or a change in cut	Tool condition, backing, contact or process values. Check the last accepted stage.	Stop the affected operation and preserve evidence for the process owner.
Finish extends into protected texture	Boundary, fixture alignment, masking or a change in tool support.	Hold the lot as required. Verify the protected zone and obtain the manufacturer's disposition.

Contain the affected work

Trace related parts by lot, tool, operator, stage and time window where applicable. Identify which checks may need repeating after authorised correction, treatment or cleaning.

Preserve a traceable decision

Record the original result, the approved disposition and any re-verification. Use the QMS for further escalation when the impact extends beyond the immediate lot. [2, 3]

09 / WORKED COUPON TRIAL

A smoother surface can still fail

Illustrative evaluation on stainless-steel training coupons. Each coupon has a flat finishing area next to a protected shoulder. The trial asks whether a change in support improves the specified texture.

01 **Match the coupon sets**
Use the same material condition, geometry and starting surface. Record the datum, points A and B, initial measurements and the approved trial limits.

02 **Change only the planned support**
Compare the established support A with candidate B. Keep the abrasive sequence and inspection methods fixed and record setup, readings and any departures.

03 **Check both acceptance criteria**
Measure texture at the defined locations and assess the protected shoulder independently. Keep the actual readings with the coupon ID.

Illustrative trial results

COUPON OUTCOME	SUPPORT A	SUPPORT B
Coupons assessed	12	12
Texture criterion met	11 / 12	12 / 12
Protected shoulder criterion met	12 / 12	10 / 12
Both criteria met	11 / 12	10 / 12

Hold the candidate pending review

The improved texture result comes with two failed shoulder checks. Preserve the failed coupons, review support and contact at the boundary, and agree any revised trial before reconsidering the change.

The counts demonstrate a decision method on training material. Device-specific qualification and cleaning evidence follow the applicable QMS.

10 / QUALIFICATION AND CHANGE CONTROL

Qualify the finishing process

When subsequent inspection cannot fully verify an output, assess the need for process validation under the manufacturer's QMS. Use an approved plan covering the equipment, variation and risks. [1-3, 6]

ACTIVITY	WHAT TO ESTABLISH	RECORD TO RETAIN
Installation qualification where used	Confirm the specified equipment, tooling, utilities, calibration and relevant documentation are in place.	Equipment ID and setup, inspections, configuration and approved record.
Operational qualification where used	Challenge the authorised operating window and relevant limits. Include permitted ranges for tool condition, fixture and cleaning inputs where applicable.	Protocol, tested ranges, data, exceptions and approved boundaries.
Performance qualification where used	Show repeatable performance under representative conditions. Cover the material, features, lots and operators required by the risk assessment.	Production-equivalent runs, all acceptance results, deviations and sign-off.
Routine control and revalidation	Monitor the approved parameters and results. Review changes for their effect on form, surface and manufacturing residues.	Control plan, ongoing data, change assessment and further evidence where required.

Route changes through the QMS

Review changes to abrasive supplier or product, backing or compound, tool or fixture, process sequence, cleaning route and measurement method. Record who decides whether verification or revalidation is required. [2, 3, 6, 8]

Define the qualified scope

Link the authorised work to the part family, material, zone, tool, media and inspection route. State the conditions that require further review.

11 / LOT RECORDS AND RELEASE

Keep lot release traceable

Reconcile the approved manufacturing record with the actual parts, lots and inspections. Use the device manufacturer's quality system and applicable customer requirements for handover. [1-3]

RECORD GROUP	WHAT BELONGS IN THE PACKET	CLOSEOUT CHECK
Identity and baseline	Part number and revision, lot or serial as required, material records, work order and applicable drawing.	Lot and counts match the traveller and scope of work.
Process and tool history	Abrasive and compound codes and traceability where required, tool setup, stage completion and approved changes.	Actual sequence and settings are traceable to the accepted process.
Inspection and cleanliness	Feature-level results, method and equipment, process stage, cleanliness or treatment reports and related evidence.	Every required characteristic has its own accepted result or approved disposition.
Exceptions and handover	Deviation, affected lots, disposition, re-verification and next operation or protected packaging where specified.	Holds resolved or segregated. Release and transfer recorded by authorised personnel.

Keep rework and re-inspection connected

Record the original result, approved work and post-rework measurements together. Follow the authorised inspection and cleaning sequence for the restored condition.

Production records

Show how the actual process was completed and which lot it covered.

Release evidence

Show the acceptance basis and decision for each required feature or report.

For device release, apply the appropriate manufacturer and market requirements. [1-3, 11]

12 / REUSABLE WORKSHEET A

Plan the finishing process

Print one copy per part family or trial. Attach the drawing, zone map and approved process and inspection plan. Enter the values and limits from the applicable controlled documents.

JOB OR TRIAL ID / OWNER / DATE

PART FAMILY / DRAWING REVISION

MATERIAL AND CONDITION / INCOMING FINISH / LOT OR COUPON IDENTIFIERS

ZONE MAP / PROTECTED FEATURES / DATUM / PERMITTED REMOVAL

STAGE OR CHECKPOINT	TOOL, MEDIA AND SETTINGS REF.	ENDPOINT AND CHECK
As-found and setup		
Permitted correction		
Scratch refinement		
Finish or treatment		
Cleaning and handover		

MEASUREMENT LOCATIONS / INSTRUMENT, METHOD AND ACCEPTANCE REFERENCES

SAMPLING SCOPE / APPROVED HOLDS / DISPOSITION ROUTE / AUTHORISED BY AND DATE

Record results on worksheet B or the controlled traveller and inspection record.

13 / REUSABLE WORKSHEET B

Record the verification evidence

Print one copy per part, coupon or lot as defined by the plan. Enter actual readings with units, or link to the applicable report.

WORK ORDER / DATE / OPERATOR

PART / LOT OR SERIAL / DRAWING REV.

STAGE / TOOL AND MEDIA ID OR LOT / FIXTURE / INSPECTION METHOD AND EQUIPMENT

FEATURE OR CHECK	LIMIT / METHOD REF.	BEFORE / STAGE	FINAL / RESULT
Geometry or edge			
Surface texture / lay			
Protected feature			
Visual condition			
Cleaning or treatment			

LOCATIONS, UNITS AND SETUP / CLEANING OR TREATMENT REPORT / CALIBRATION REF.

Verify the required handover checks

- ☐ Specified geometry, finish, protected zones and cleanliness checks are recorded.
- ☐ Part or lot, media and process records are traceable as required.
- ☐ Hold, rework and re-verification records are attached where applicable.

DEVIATION OR DISPOSITION / EVIDENCE REFERENCES / NEXT OPERATION

VERIFIED BY / DATE / TIME

AUTHORISED STATUS / RELEASE OR HOLD REF.

Use the manufacturer's controlled process for lot disposition and device release.

14 / TECHNICAL REFERENCES

Source notes and further reading

Check the current revision of the governing job documents. Select the references and handbook chapters below for supporting information.

[1] Malaysia MDA | Conformity assessment for medical devices OPEN
Malaysian guidance on conformity assessment and quality-system evidence.

[2] ISO 13485 | Medical device quality management systems OPEN
Quality management system requirements for regulatory purposes.

[3] GHTF | Medical device process validation guidance OPEN
Verification and validation decisions, qualification and revalidation.

[4] NIST | Surface roughness and step height calibrations OPEN
Measurement conditions and uncertainty for surface texture.

[5] ISO 21920-2 | Profile surface texture OPEN
Definitions and parameters. Use the specification called up for the part.

[6] ASTM F3127 | Manufacturing cleaning validation OPEN
Considerations for validating cleaning during medical device manufacture.

[7] ISO 19227 | Cleanliness of orthopaedic implants OPEN
Cleaning validation and controls within the standard's scope.

[8] U.S. FDA | Biological evaluation and ISO 10993-1 OPEN
Risk-based biological evaluation guidance for applicable devices.

[9] ASTM F86 | Metallic surgical implant surface preparation OPEN
Surface preparation and marking within the standard's scope.

[10] FEPA | Abrasive product safety publications OPEN
Safe use information for the applicable abrasive product family.

[11] U.S. FDA | Quality Management System Regulation OPEN
U.S. quality-system information where applicable to the device.

MKTECH Industrial Abrasives Handbook

022 Surface finish fundamentals →
023 Surface roughness →
024 Scratch refinement →
028 Polishing fundamentals →

Developed from MKTECH-TA-MED-008. Images are illustrative and come from the supplied guide. Web references accessed November 2026.

15 / MKTECH APPLICATION SUPPORT

Share the feature and finish

MKTech Industry Sdn Bhd supports abrasive selection and supply enquiries from Petaling Jaya, Malaysia. Share the permitted application details and the results the process must produce.



DEFINE THE APPLICATION

What must the surface do?

Provide the material, feature, protected areas and required finish. Include the current tool and media and the verification or cleaning requirements that affect the enquiry.

Include these details with the request

Component and zone

Permitted drawing details, alloy, starting finish, protected features and work scope.

Tool and sequence

Current abrasive and grade, support, stage sequence and cleaning constraints.

Evidence and supply

Inspection criteria, approved trial scope, quantity and delivery location.

Contact MKTECH →

Browse products →

Open handbook →

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Keep process approval with the manufacturer

MKTECH can discuss abrasive product specifications and supply. The responsible manufacturer controls device requirements, qualification, inspection and release.