



Dental Device Maker Kit (Aligners / Implants / 3D Printing)

ISO 13485 add-ons for aligners, implants and 3D-printed dental devices.

What's inside

File	What it is / how to use it
01_Dental_Device_Maker_Workbook.xlsx	Classification worksheet, 3D print build log, resin lot register and validation tracker.
02_Dental_Device_QMS_Addendum.docx	Add-on procedure for digital dental manufacturing.
03_Patient_Specific_Device_Record.docx	Device history record for patient-specific devices.

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About the author

Built by Matt Norman, US Navy veteran and former SpaceX Falcon 9 quality inspector and QA supervisor. (Not affiliated with or endorsed by SpaceX.) Norman Quality Tools is Veteran-Owned & Operated. Contains no SpaceX, government, or customer proprietary information; all example data is made up.

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ISO 13485 Addendum for Dental Devices

Dental Device Maker Kit (Aligners / Implants / 3D Printing) - Document 02 - Rev A (2026-10)

1. Purpose and scope

Extend [Company]'s ISO 13485 QMS to digital dental manufacturing: scans, design software, 3D printing, thermoforming and implant processing.

2. Responsibilities

Role	Responsibility
Quality manager	[Define]
Approver	[Define]

3. Procedure

1. Control incoming scans and Rx data (completeness, identity).
2. Validate design software and printer/resin combinations.
3. Record resin lots and post-processing per build.
4. Inspect fit/dimensions per device type.
5. Handle complaints and MDR decisions per the complaint procedure.

4. Records

- Build logs
- Validation records
- Inspection records

5. Revision history

Rev	Date	Change	Approved

Role	Name	Signature	Date
Prepared by			
Approved by			

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