

Step-by-Step Guide: DENTAL LABORATORY NOTIFICATION PROCESS

MEDICAL DEVICES CLUSTER OCTOBER 2022



Local standalone dental laboratories that manufacture only custommade Class A and/or Class B dental devices will no longer require a Manufacturer's Licence.

They will only be required to:

- Have a Quality Management System in place for their manufacturing site (no certification required), and
- Submit a **one-time notification** to HSA

The Dental Laboratory Notification Steps are detailed in the following slides.

To find out more about the regulatory controls on custom-made dental devices, please visit https://www.hsa.gov.sg/announcements/regulatory-updates/webinar-on-dental-laboratory-regulatory-requirements-in-singapore.



Access the Dental Laboratory Notification form on your mobile or desktop

https://go.gov.sg/dentallab-notification



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Login with your corporate linked SingPass ID (You will be redirected to the SingPass login page.)

Dental Laboratory Notification Form

O 5 mins estimated time to complete

LOGIN WITH SINGPASS (CORPORATE) -

Corporate entity login is required for this form. Your Singpass ID and corporate Entity ID will be included with your form submission.



Input your company's UEN

1. Unique Entity Number (UEN)

Your company's 10 digit UEN as issued by ACRA (Accounting and Corporate Regulatory Authority)

Enter UEN



Input name and address of dental laboratory

2. Manufacturing Site Name

If your company has more than one manufacturing site, please input only one manufacturing site name. Please submit one form per manufacturing site.

3. Manufacturing Site Address

If your company has more than one manufacturing site, please input only the address for the manufacturing site indicated above. Please submit one form per manufacturing site.



Select all applicable dental device type(s)

4. Scope of manufacture
Please select ALL applicable custom-made dental device types manufactured under the site.
Bridge
Inlay, Onlay
Crown
Complete / Partial Dentures
Retainers
Aligners
Others
If others, please specify.



Input your name and contact email

(You will be required to verify your email address by inputting a One-Time Password (OTP) sent to your email)

5. Contact Person Name	
6. Contact Email	
me@example.com	VERIFY



Verify your email address by inputting the 6 digit OTP





Step 7: Declaration

Complete the declaration

Declaration			
7. I declare that the above manufacturing site only manufactures custom- made Class A and/or Class B dental devices.			
× NO	✓ YES		
8. I declare that the above manufacturing site has a Quality Management System in place.			
× NO	✓ YES		
9. I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.			
× NO	✓ YES		



Ensure all fields are populated accurately and click Submit

9. I attest that the information submitted is true and accurate, and that I am authorized to submit this form on behalf of the company.

× NO	✓ YES		
SUBMIT			





You should receive an acknowledgement sent to your registered email

 Subject: Acknowledgement of Dental Laboratory Notification Sender Name: Medical Devices Cluster
Response ID: 123456789
Dear Sir or Madam,
We have received the notification form for your dental laboratory. We will be in touch via email if there are any clarifications required.
If there are any changes to this manufacturing site scope, please submit a new form for this site. A new form entry will overwrite all previous entries for the site.
Regards, Medical Devices Cluster Health Products Regulation Group Health Sciences Authority, Singapore





For clarifications regarding the notification form, please email <u>HSA_MD_Info@hsa.gov.sg</u> with the email subject "Dental Laboratory".