



Certificate No. MD-QMS/91/R/I/2735/b

This is to certify that

## AMPA Orthodontics Private Limited

**Registered Office : 1<sup>st</sup> Floor, Empire Plaza B Wing, Lal Bahadur Shastri Marg, Vikhroli (West), Mumbai - 400 083, Maharashtra, India**

(a list of certified workplaces is contained in Annexure which is inseparable part of this Certificate)

has been found to conform to the requirements of  
Medical Devices - Quality Management System Standard

### ISO 13485:2016

This certificate is valid for the following scope :

- Design and Development, Manufacture and Sales of Dental Aligners Kit and Impression Kit
- Design and Development, Manufacture and Sales of Dental Accessories : Aligner Chewie, Cheek Retractor and Aligner Retriever

Technical Area/s (Ref. IAF MD9) :  
A.1.1

Initial Certification : 11/02/2022  
Valid until : 10/02/2025  
Modified on : 19/02/2022, 09/03/2023  
(Replaces withdrawn Certificate No. MD-QMS/91/R/I/2735/a issued on 19<sup>th</sup> February, 2022)



The authenticity of this document may be re-affirmed by writing to [certification@zenith-worldwide.com](mailto:certification@zenith-worldwide.com). Lack of fulfillment of conditions as set out in the Certification Agreement may render this certificate invalid. Any alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of law.

**Accreditation Body: International Accreditation Service, Inc.**  
3060 Saturn Street, Suite 100, Brea, California 92821-1732 U.S.A.  
[www.iasonline.org](http://www.iasonline.org)

**Issuing Authority: Zenith Quality Assessors Pvt. Ltd.**  
Office No. 01A, B-Wing, Siddhesh OPTIMUS, S. No. 211,  
Viman Nagar, Pune – 411 014, Maharashtra, India  
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Annexure to Certificate No. **MD-QMS/91/R/I/2735/b**

Issued to the Company

**AMPA Orthodontics Private Limited**

**Scope of Certification :**

- Design and Development, Manufacture and Sales of Dental Aligners Kit and Impression Kit
- Design and Development, Manufacture and Sales of Dental Accessories : Aligner Chewie, Cheek Retractor and Aligner Retriever

**Workplaces and Scope of Activities :**

Registered Office : 1<sup>st</sup> Floor, Empire Plaza B Wing, Lal Bahadur Shastri Marg, Vikhroli (West),  
Mumbai - 400 083, Maharashtra, India

Scope of Activities : Legal

Site 1 : Chintamani Plaza, Ground, 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> & 6<sup>th</sup> Floor, Besides Western Express  
Highway Metro Station, Andheri Kurla Road, Andheri East, Mumbai - 400 099,  
Maharashtra, India

Scope of Activities : Management, Purchase, Human Resource, Sales & Marketing, Design &  
Development, Production, Quality Control, Quality Assurance & Customer Support

Site 2 : Mehta Industrial Estate, Ground & 1<sup>st</sup> Floor, Besides Western Express Highway  
Metro Station, Andheri Kurla Road, Andheri East, Mumbai - 400 093,  
Maharashtra, India

Scope of Activities : Production, Quality Control, Quality Assurance, Stores & Dispatch

Initial Certification : 11/02/2022

Valid until : 10/02/2025

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