



Certificate No. MD-QMS/91/R/II/2735/c

This is to certify that

AMPA Orthodontics Private Limited

Registered Office : 1st 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
- 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 : 29/02/2024

(Replaces withdrawn Certificate No.MD-QMS/91/R/II/2735/b issued on 09/03/2023)



The authenticity of this document may be re-affirmed by writing to 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.
3080 Saturn Street, Suite 100, Brea, California 92821-1732 U.S.A.
www.iasonline.org

Issuing Authority: Zenith Quality Assessors Pvt. Ltd.
Office No. 01A, B-Wing, Siddhesh OPTMJS, B. No. 211,
Viman Nagar, Pune - 411 014, Maharashtra, India
www.zenith-worldwide.com



Annexure to Certificate No. **MD-QMS/91/R/II/2735/c**

Issued to the Company

AMPA Orthodontics Private Limited

Scope of Certification :

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

Workplaces and Scope of Activities :

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

Scope of Activities : Legal, Management, Human Resource, Sales & Marketing

Site 1 : Chintamani Plaza, Ground & 6th Floor, Besides Western Express Highway Metro
Station, Andheri Kurla Road, Andheri East, Mumbai - 400 099, Maharashtra, India

Scope of Activities : Management, Human Resource, Purchase, Design & Development, Production &
Customer Support

Site 2 : Mehta Industrial Estate, Ground & 1st 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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