



# EC CERTIFICATE

## Modern Orthodontics

2024 Gobind Nagar  
Circuit House Road  
Ludhiana 141001 India

## Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:  
**Design and Manufacture of Orthodontic Appliances**

Device Classification:  
**Ila**

Device Descriptions:  
**Orthodontic Devices for braces used for dental correction**

Model Type:  
**See Attachment 1**

Manufacturing Site located:  
  
Mullanpur Road, Hambran Industrial Area Village  
Hambran, District Ludhiana, 141010 India

**We hereby declare that an examination of the full quality assurance system has been carried out per report 11646554 , following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC, Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with (1) attachments listing model covered by this certificate.**

File Number A28401  
Certificate No. 799.170331

Cycle Start Date 31 March 2017  
Effective Date 31 March 2017  
Expiry Date 30 March 2022

Authorised by

**Deborah Stubbs**  
Certification Manager

For and on Behalf of UL International (UK) Ltd

## Notified Body

# 0843



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### Attachment 1 of 1

The products detailed below are covered under the scope of this certificate

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Orthodontic Appliances	Orthodontic	Bracket	Ila	
		Archwire	Ila	
		Ligature	Ila	
		Appliance System	Ila	
		Appliance and Related Equipment	Ila	
		Elastic Band	Ila	
		Band	Ila	
		Tube	Ila	
		Wire	Ila	
		Band Material	Ila	
		Band Preformed	Ila	
		Space Maintainer	Ila	
		Band Elastic	Ila	
		Clamp, Wire	Ila	
		Spring	Ila	
Bracket, Metal	Ila			

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