

# EU Quality Management System Certificate IN24/00000169

The management system of

## Modern Orthodontics

2024, Gobind Nagar, Circuit House Road, Ludhiana, Punjab 141001, INDIA

SRN Number: IN-MF-000009197

has been assessed and certified as meeting the requirements of

### MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 14 February 2024 until 14 February 2029 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 14 August 2028

Issue 1. Certified since 14 February 2024

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

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Global Medical Device Certification  
Manager

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# Modern Orthodontics

## MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa devices

MDN1209

Orthodontic Appliance System intended to correct malocclusions and/or structural flaws of teeth and/or jaws.

- Orthodontic Brackets (Stainless Steel & Ceramic) (Basic UDI-DI: 89043763BracketsNK)
- Orthodontic Molar Tubes (Basic UDI-DI: 89043763MolarTubes5Y)
- Orthodontic Molar Bands (Basic UDI-DI: 89043763MolarBandsV4)
- Orthodontic Wires (Stainless Steel, Ni-Ti, Beta Titanium) (Basic UDI-DI: 89043763WiresFZ)
- Orthodontic Elastomerics (Basic UDI-DI: 89043763ElastomericsKH)
- Orthodontic Accessories (Lingual Buttons, Cleats, Sheaths, Direct Bond Eyelets, Springs, Hooks) (Basic UDI-DI: 89043763AccessoriesAE)

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation:

N/A

Certification is based on following reports: - IN/MUM/962458 - S2A 1.2

Authorized representative name and address (if relevant): International Ventur, s.a. Polygono Industria Ciudad Del Transporte C/Luxemburgo, 75, 12006, Castellon, Spain

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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# Modern Orthodontics



## MDR EU Quality Management System certificate (Annex IX QMS)

Issue 1
<b>Sites</b>
Modern Orthodontics Registered Office: 2024, Gobind Nagar, Circuit House Road, Ludhiana, Punjab 141001, INDIA
Modern Orthodontics Works: Mullanpur Road, Hambran Industrial Area, Village Hambran, District Ludhiana, Punjab 141110, INDIA

