EU Quality Management System Certificate US23/00000342

The management system of

Reliance Orthodontic Products, Inc.

1540 West Thorndale Avenue, Itasca IL 60143, United States of America
SRN Number: US-MF-000013812
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 10 August 2023 until 27 July 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 January 2028
Issue 2. Certified since 27 July 2023

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
SGS Belgium NV NB 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

Reliance Orthodontic Products, Inc.

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa devices
MDN1209
Non Sterile
Orthodontic Adhesives -Bonding Resin (Light / Heat Cure)
(B-UDI: D798ADHESIVELIGHTCUREJF)
Ancillary Bonding Materials (Primers, Conditioners, Etchants, sealants- pre-applied for better adhesion as needed)
(B-UDI: D798CONDITIONERPRIMERKE)
Wires and Metal Mechanical Devices and Mechanical Positioning Hardware
(B-UDI: D798ORTHOHARDWAREEX)
Orthodontic Aligner Accessories (Bonding to Aligners, Cover Blank Space in Aligner for missing or mis-shaped tooth)
(B-UDI: D798ORTHOALIGNER9U)
Orthodontic Adhesives (Time / Chemical Cure)
(B-UDI: D798ADHESIVECHEMCURES7)
Orthodontic Elastics
(B-UDI: D798ELASTICSDW)

Class IIa Device
MDN 1208
Non Sterile
Polishing Tools / Removal Accessories (Adhesive Removal Bur, Polishing Points)
(B-UDI: D798ORTHOPOLISHREMOVEYN)

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: - WW/MC/618388 - CTC 1.14
Authorized representative Name and address (if relevant): Emergo Europe -The Netherlands, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

Previous certificate number: N/A
Change in between this certificate and previous one: Scope and company name correction.