# EU Quality Management Certificate

This is to certify that the company

## SprintRay Inc.

2710 Media Center Drive, Suite #100A
Los Angeles, CA 90065
United States of America

SRN: US-MF-000036081

has established, implemented and maintains a Quality Management System in accordance with

## Annex IX, Chapter I and III of the Regulation (EU) 2017/745

**Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation**

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

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|---|---|
| Certificate registration no. | 31622718 MDR2017Q |
| Certificate ID | 1000318152 |
| Effective date | 2026-08-17 |
| Expiry date | 2030-04-29 |
| Frankfurt am Main, | 2026-08-17 |

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

**DQS Medizinprodukte GmbH**

Sven Hoffmann
Managing Director

# Annex to EU Quality Management Certificate
# SRN of Manufacturer: US-MF-000036081
# Certificate ID: 1000318152

## Authorised Representative of the company:

## SprintRay Europe GmbH

Brunnenweg 11
64331 Weiterstadt
Germany

SRN: DE-AR-000033436

**Device categories and variants covered by this certificate according to Article 52:**

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|---|---|
| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | OnX Tough 2 |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850039704SRI-0202164HG |
| Intended purpose: | SprintRay OnX Tough 2 is a tooth shade ceramic-hybrid resin used for the fabrication of hybrid denture prosthetics, implant-supported denture prosthetics, monolithic full and partial removable dentures, and preformed denture teeth to be used in a denture. |

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|---|---|
| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | Ceramic Crown |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850039704SRI-0202057HE |
| Intended purpose: | SprintRay Ceramic Crown is a light-curable polymerizable resin intended to be used for the fabrication of; individual and fixed definitive full single crowns; definitive partial crowns in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures; and individual and removable monolithic full and partial dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material. |

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|---|---|
| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | APEX Base |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850039704SRI-0202153HB |
| Intended purpose: | APEX Base resin is a light-curable polymerizable resin intended to be used for the fabrication and repair of full and partial removable dentures and baseplates. The material is an alternative to traditional denture base material. |

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| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | APEX Teeth |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850039704SRI-0202157HK |
| Intended purpose: | APEX Teeth is a light-curable polymerizable resin intended to be used to fabricate artificial teeth for full and partial removable dentures. This material is an alternative to traditional denture teeth material. |

# Annex to EU Quality Management Certificate
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|---|---|
| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | Crown HT |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850070544SRI-0204030D3 |
| Intended purpose: | Crown HT is a light-curable polymerizable resin intended to be used for the fabrication of; individual and fixed definitive full single crowns; definitive partial crowns in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures; and individual and removable monolithic full and partial dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material. |

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|---|---|
| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | APEX Flex |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850070544SRI-0202187DP |
| Intended purpose: | SprintRay APEX Flex is an alternative to traditional thermoplastic material used for the fabrication and repair of partial dentures. It is intended exclusively for professional dental work. |

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|---|---|
| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | Digital Temp |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850039704SRI-0204020H5 |
| Intended purpose: | SprintRay Digital Temp is a light-curable resin indicated for the fabrication of individual and fixed temporary full single crowns, temporary partial crowns, and temporary bridges. The material is an alternative to traditional restorative dental material. |

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|---|---|
| Device category: | **MDN 1209 - Non-active non-implantable dental materials** |
| Product name: | Midas Restore |
| Risk classification: | IIa |
| Basic-UDI-DI: | 0850070544SRI-0204159DY |
| Intended purpose: | Midas Restore is a light-curable polymerizable resin intended to be used for the fabrication of individual and fixed definitive full single crowns; definitive partial crowns (e.g., inlays, onlays) in anterior and posterior area, individual and fixed single veneers; artificial teeth for dental prostheses, which are used for removable definitive full dentures in dental offices and laboratories. The material is an alternative to traditional restorative dental material. |

**Examinations and tests performed:**
31622718_A215301MED_01 dated 2024-10-19
31622718_A215326MED_02 OnX Tough 2 dated 2025-04-11

**Further conditions for or limitations to the validity of the certificate:**
n/a

**Reference to previous certificates:**

| Version | Date of Issue | Certificate-ID | Description of change |
|---|---|---|---|
| 01 | 2025-04-30 | 1000186243 | Change of Basic UDI-DI |
| 02 | 2025-08-07 | 1000258589 | Addition of products Apex Base, Apex Teeth, Crown HT |
| 03 | 2025-11-17 | 1000267003 | Addition of products Apex Flex, Digital Temp |
| 04 | 2026-04-17 | 1000302773 | Addition of product Midas restore |