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-MF000036081

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.

Certificate registration no.	31622718 MDR2017Q
Certificate ID	1000267003
Effective date	2025-11-17
Expiry date	2030-04-29
Frankfurt am Main,	2025-11-17

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF000036081
Certificate ID: 1000267003

Authorised Representative of the company:

SprintRay Europe GmbH

Brunnenweg 11
64331 Weiterstadt
Deutschland

SRN: DE-AR-000033436

Device categories and variants covered by this certificate:

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.

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.

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.

Annex to EU Quality Management Certificate
SRN of Manufacturer: US-MF000036081
Certificate ID: 1000267003

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.

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.

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:

Revision	Date of Issue	Certificate-ID	Description of change
01	2025-04-30	100186243	Change of Basic UDI-DI
02	2025-08-07	1000258589	Addition of products APEX Base, APEX Teeth, Crown HT