EU Declaration of Conformity

We – SprintRay Inc. (SRN: US-MF-000036081) – being the manufacturer of

NightGuard Firm 2 consisting of
(products are listed in Annex)

declare under our sole responsibility that the products

conform to the requirements of Medical Device Regulation (EU) 2017/745, other relevant Union legislation and amendments and meet the relevant General Safety and Performance Requirements of Annex I of the MDR, the Regulation (EC) No 1907/2006 (REACH).

All devices are designed, manufactured, tested, and released for sale in accordance with the Technical Documentation (according to Annex II MDR), the applicable standards, and common specifications (CS).

The conformity assessment procedure was performed following Annex IV (V) of Medical Device Regulation (EU) 2017/745.

Device Classification
Medical Device Class I - according to Annex VIII, Rule 5.

The list of applied standards and common specifications is part of the Technical Documentation and can be seen upon request.
Common Specifications: N/A

SprintRay Inc. meets the requirements of Medical Device Regulation (EU) 2017/745 Art. 10 and maintains a quality management system that complies with the Medical Device Regulation.

The appointed EU-Authorised Representative is SprintRay Europe GmbH, based in Brunnenweg 11, 64331 Weiterstadt, Germany (SRN: DE-AR-000033436).

Electronically signed by: Sara Moghtadernejad
Reason: I have reviewed and approve this document.
Date: Sep 10, 2026 17:16:39 PDT

09/10/2026

Sara Moghtadernejad
Global Director of Regulatory Affairs & Quality Assurance (Mgmt. Rep.- PRRC)
SprintRay Inc.
2710 Media Center Dr Suite #100A
Los Angeles, CA 90065
USA

ANNEX

Product Family	Product Name / Description	Intended Purpose	Class	Basic UDI-DI	Rule	GMDN Code	SKU#
Dental Resin	NightGuard Firm 2 (Midnight Purple)	SprintRay NightGuard Firm 2 is indicated for the fabrication of dental appliances such as mouthguards and nightguards.	I	0850039704SRI-0202147HG	Rule 5	16730	SRI-0202147

PMS activities are planned, executed, followed up and documented for all products in scope of this declaration of conformity according to Medical Device Regulation (EU) 2017/745, Annex III.

Document Number	Revision	Description	Effective Date
DoC-012-EU	1	Initial Release	04/17/2025
DoC-012-EU	2	Update temple; clerical edits	09/11/2026

DoC-012-EU_2 - NightGuard Firm 2 EU Declaration of Conformity

Final Audit Report 2026-09-11

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