

### Certificate number

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2018-05-13

Cycle start date

2024-05-13

Effective date

2025-04-28

**Expiry date** 

2027-05-12





# **Planet DDS**

159 S Main St Suite 414 Akron, Ohio 44308 UNITED STATES

Facility ID: F001387

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016 EN ISO 13485:2016/A11:2021

with additional regulatory requirements listed on the final page of this certificate.

Design, development and distribution of software dental imaging programs for image storage, diagnostics, notes, measurement, labels, and additional aspects regarding oral images and X-rays for the area of dental.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

P. Dayul

Paul Daysh Operations manager – Medical Regulatory



Check certificate status: here

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

UL LLC, UL Solutions medical regulatory services is an MDSAP Recognized Auditing Organization

UL LLC 333 Pfingsten Road Northbrook, IL 60062-2096 USA



# Addendum 1

Site	Company Name	Location		Performing
1-1	Planet DDS	159 S Main St		
		Suite 414		
		Akron		
		Ohio		
		44308		
		UNITED STATES		
			Facility ID:	



# **Additional Regulatory Requirements**

## **Planet DDS**

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#### Canada:

- Medical Devices Regulations - Part 1- SOR 98/282

#### **United States:**

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 Subparts A to D
- 21 CFR 821 (where applicable)

