

### **Planet DDS**

313 S High St. Suite 200 Akron, Ohio 44308 UNITED STATES

Facility ID: F001387

UL Medical Regulatory Services of UL LLC<sup>®</sup>(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

## ISO 13485:2016

with additional regulatory requirements listed on 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.



Authorized by

**Paul Hilgeman** 

Director & Global Industry Leader, Medical CMIT – Medical Regulatory

Check Certificate Status: <u>here</u>

File Number Certificate Number Initial Issue Date A28281 1421.230513 May 13, 2018

Cycle Start Date Effective Date Expiry Date May 13, 2021 May 13, 2023 May 12, 2024

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



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

# **CERTIFICATE OF REGISTRATION**



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#### **Additional Regulatory Requirements**

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)

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