### Certificate

# Quality Management System EN ISO 13485:2016

Registration No.: SX 2041251-1

Certificate Holder: Aidite (Qinhuangdao) Technology Co., Ltd.

No.9 Dushan Road, Economic And Technological Development

Zone, Qinhuangdao City,

066004 Hebei P.R. China

Scope: Design and Development, Manufacture and Distribution of

Dental Zirconia Ceramic, Dental Glass Ceramic, Coloring Liquid Specialized for Aidite Zirconia Material, Porcelain Powder, PMMA Blocks for Dental Use, Progressive Orthodontic Appliance System, Denture base resin,

Dental ceramic blocks, Dental Foil, Dental Resin for Additive Manufacturing, Intraoral Scanner, Additively Manufactured

**Denture Base Resin** 

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

 Report No.:
 10924174-100

 Effective date:
 2024-07-10

 Expiry date:
 2027-07-09

 Issue date:
 2024-07-09

Replaces certificate SX 2041251-1 issued 2023-09-06

Samuel Qin TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com





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The scope of certification also covers the following sites:

#### No. Facility

/01 c/o Aidite (Qinhuangdao) Technology Co., Ltd.

No.9 Dushan Road, Economic And Technological Development Zone, Qinhuangdao City,

066004 Hebei P.R. China

/02 c/o Aidite (Qinhuangdao) Technology

Co., Ltd.

No. 56 Tianchi Road, Economic And Technological Development Zone,

Development Zone Qinhuangdao City, 066004 Hebei P.R. China

#### Scope

Design and Development, Manufacture and Distribution of Dental Zirconia Ceramic, Coloring Liquid Specialized for Aidite Zirconia Material, Intraoral Scanner, Additively Manufactured Denture Base Resin:

Design and Development, Distribution of Dental Glass Ceramic, Progressive Orthodontic Appliance System, Denture base resin, Dental ceramic blocks, Dental Foil, Dental Resin for Additive Manufacturing

Manufacture of Dental Glass Ceramic and Progressive Orthodontic Appliance System, Dental Foil, Dental Resin for Additive Manufacturing, Porcelain Powder, PMMA Blocks for Dental Use

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Issue date: