

**Business Stream Products
Certification Department**



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Huanghua Promisee Dental
Co., Ltd.
Mould Industry Garden
Empolder Section
Huanghua
061100 HEBEI
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date November 05, 2019

Application for : QMS
Certificate No. : SX 60143037 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the new certificate No. SX 60143037 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body


Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Chairman of the
Supervisory Board

Dipl.-Ing.
Ralf Scheller

Nuremberg HRB 26013
VAT No.: DE 811835490

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60143037 0001
Report No.: 16803471 009

Organization: Huanghua Promisee Dental
Co., Ltd.
Mould Industry Garden
Empolder Section
Huanghua
061100 Hebei
China

Scope:

Products:

Disposable Dental Air Water Syringe Tips, Disposable Saliva Ejectors, Mixing bowl, Silicone Rubber Mixing Tips, Dental Retractor, Denture Box, Cotton Roll Dispenser, Bur Holder Box, X-ray Film Holder, Dental Material Bullet Dispenser, Disposable Mouth Mirror, Micro Applicator, Impression Tray, Gingival Brushes, Dental Wedge, Spatula, Safety Glasses Face Shield with Frame, Medical Plastic Trays, Dental Impression Material Syringe, Dental Sectional Contoured Matrices Kits, Dental Bib Clip, Orthodontic Material Device, Clamping Ring for Dental Use, Rim Former for Dental Use, Dental Implant Guide System Kits

Certification Body



Date: 2019-11-05



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Huanghua Promisee Dental
Co., Ltd.**
**Mould Industry Garden
Empolder Section
Huanghua
061100 Hebei
China**

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices
(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-11-05
Certificate Registration No.: SX 60143037 0001
An audit was performed. Report No.: 16803471 009
This Certificate is valid until: 2020-09-16

Certification Body



Date 2019-11-05



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>