

## CE Technical Documentation Review Report

Applicant:

**Huanghua Promisee Dental Co.,Ltd**  
Mould Industry Garden ,Empolder  
Section,Huanghua,Hebei Province,061100,  
P.R.China

Report Number:

16803080.001

Examination intent:

Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s):

(See attachment)

Type(s)/Model(s):

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Classification:

**Class I**  
(according to manufacturer's declaration)

Examination period:

Feb.13.2021

Date of expiry:

Feb.12.2026

Review result:

During the examination of the provided Technical Documentation (No.: KT-CE-TF, Revision: B/0, dated 2014-01-18 ), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd.

Yuhong CHEN  
Manager  
Medical Services



Rev.01, 2002-10-10

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### Attachment to

Report Number: 16803080.001

Applicant: Huanghua Promisee Dental Co.,Ltd  
Mould Industry Garden ,Empolder Section,Huanghua,Hebei  
Province,061100, P.R.China

Product(s): Micro applicator  
Denture box  
Impression Tray  
Mixing bowl  
Dental retractor  
Silicone rubber Mixing Tips  
Gingival Brushes  
Poly wedge  
Cotton roll dispenser  
Spatula  
**Safety glasses face shield with frame**  
Bur holder box  
Universal barrier film  
Medical plastic trays  
Dental material bullet dispenser  
X-ray film holder  
Dental impression material syringe  
Dental material Glassware

Type(s)/Model(s): ----

Examination period: Feb.13.2021

Date of expiry: Feb.12.2026

TÜV Rheinland (China) Ltd. Beijing Operation

  
Yuhong CHEN  
Manager (Beijing Operation)  
Medical Services

Rev.01, 2002-10-10

Unit 707, AVIC Bldg., No. 10B, Central Road, East 3rd  
Ring Road, Chaoyang District, Beijing, 100022, P.R.China

Tel: (8610)6566 6660 Fax: (8610)6566 6667  
e-mail: [info@bj.chn.tuv.com](mailto:info@bj.chn.tuv.com) Internet: <http://www.chn.tuv.com>