

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): -----

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

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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): -----

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TÜV Rheinland (China) Ltd. Beijing Operation



Yuhong CHEN
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