

CE Technical Documentation Review Report

Applicant: **Huanghua Promisee Dental Co., Ltd.**
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Report Number: **50187084-001**

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): **Dental Wedge**
Cotton Roll Dispenser
Spatula
Safety Glasses Face Shield with Frame
Bur Holder Box
Universal Barrier Film
Medical Plastic Trays

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

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

Examination period: Nov.14.2018

Date of expiry: Nov.14.2023

Review result: During the examination of the provided Technical Documentation (No.: KT-CE-TF08, Revision: B/1, dated 2018-03-10; KT-CE-TF09, Revision: B/1, dated 2018-02-07; KT-CE-TF10, Revision: B/1, dated 2018-05-10; KT-CE-TF11, Revision: B/1, dated 2018-04-07; KT-CE-TF12, Revision: B/1, dated 2018-04-07; KT-CE-TF13, Revision: B/1, dated 2018-01-26; KT-CE-TF14, Revision: B/1, dated 2018-05-26), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

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