

黄骅市康田医疗器械有限公司
HUANGHUA PROMISEE DENTAL CO., LTD
中国河北省黄骅市开发区模具城, 邮编: 061100
MOULD INDUSTRY GARDEN EMPOLDER SECTION HUANGHUA CITY HEBEI PROVINCE CHINA

EC DECLARATION OF CONFORMITY

Munufacture's Name :HUANGHUA PROMISEE DENTAL CO., LTD
Munufacture's Address : MOULD INDUSTRY GARDEN EMPOLDER SECTION HUANGHUA CITY
HEBEI PROVINCE CHINA

European Representatives : KINGSMEAD SERVICE LIMITED
145-157 St John Street, London, EC1V 4PY(UK)

Name of Device : Micro Applicator, Denture Box, Impression Tray, Mixing Bowl, Dental Retractor,
Silicone Rubber Mixing Tips, Gingival Brushes, Dental Wedge, Cotton Roll
Dispenser, Spatula,Safety Glasses Face Shield with Frame, Bur Holder Box,
Univeral Barrier Film, Medical Plastic Trays, Dental Material Bullet Dispenser,
X-ray Film Holder, Dental Impression Material Syringe, Dental material
Glassware, Disposable Mouth Mirror, Dental Bib Clip, Dental Acrylic Organizer
Holder

Brand: PRIMA.

Type : dental instrument

Classification : Class 1, non sterile

Conformity Assessment Procedure : Annex VII

Conformity Route : manufacturer' declaration

We herewith declare in our own responsibility that the above--mentioned product(s) with CE mark meet the provisions of the ED Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC ,All supporting documentations are retained Under the premise of manufacturer (head of Quality department).

General applicable directive : Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

Standard: All applicable harmonised standard (published in the Official Journal of the European Communities)

Notify Body: TUV Product Service GmbH, Ridlerstr.65,D-80339 Munich, Germany

Certificate: 50187083-001

Date CE Certificate is Expired: Nov.14, 2018

Cert valid until : Nov.14, 2023

Signature and Company seal

Name:Emily

Position:Business Manager

