

**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers:
Name and address of the manufacturer:

Huanghua Promisee Dental Co.Ltd
Mould Industry Garden, Empolder Section,
Huanghua 061100, Hebei China
SRN: CN-MF-000014766

Authorized representative of the European
Union:

MedNet EC-REP GmbH
Borkstrasse 10 · 48163 Muenster · Germany
SRN:DE-AR-000000002

the medical device:

Group name: Instrument provision tool
Product name: Denture box
Basic UDI-DI:69544540DEBO001HR
Cotton roll dispenser
Basic UDI-DI:69544540CORD001QD
Bur holder box
Basic UDI-DI:69544540BUHB001NE
Medical plastic trays
Basic UDI-DI:69544540MEPT001UF
Dental Acrylic Organizer Holder
Basic UDI-DI:69544540DAOH001K3
(alternative name and type see attachment)

of class:

Class I

according to Rule 1 of annex VIII of Regulation (EU)2017/745

Meet the provisions of the Regulation (EU)2017/745 and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:

Annex II+III of Regulation (EU) 2017/745

We, the manufacturer herewith declare under our sole responsibility that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following list of applied standards .

EN ISO 14971: 2019
EN 62366-1:2020
EN ISO 13485 :2016

EN ISO 15223-1: 2021
EN ISO 10993-5:2009
EN1639:2009

EN 1041:2008+A1:2013
EN ISO 10993-10:2013
MEDDEV 2.7/1 rev 4

ISO 10993-1: 2018
ISO 7405:2018
MEDDEV 2.12-2 rev 2

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

Huanghua City, 2021.09.26

Ort / Datum / Place, date /
Lieu, date / Luogo, data

He Qingshan, General manager

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

Product Specification List

Group name	Product name	Model	Product specification
Instrument provision tool	Denture box	DB01,DB02,DB03,DB04, DB05,DB06,DB07,DB08. DB09,DB10,DB11,DB12,DB13 DB15,DB17,DB20	/
Instrument provision tool	Denture box	DB14, DB14B	Membrane Box
Instrument provision tool	Denture box	DB16	Milk Teeth Box
Instrument provision tool	Cotton roll dispenser	CD01,CD02,CD03, CD05	/
Instrument provision tool	Cotton roll dispenser	CDM	Cotton Roll Clip
Instrument provision tool	Bur holder box	BB01,BB02,BB03,BB09	/
Instrument provision tool	Bur holder box	BF01	Bur Holder Frame
Instrument provision tool	Bur holder box	BF06	Grinding Carriage
Instrument provision tool	Bur holder box	BC01	/
Instrument provision tool	Medical plastic trays	AK01, AK01 16, AK01 16a, AK01 17, AK01 18, AK01 19, AK01 20, APT01,DPT01,DPT02,DPT03,DPT04	/
Instrument provision tool	Medical plastic trays	NC01	Neaten Case
Instrument provision tool	Dental Acrylic Organizer Holder	TH02,TH02L,TH02S	Resin Syringe Holder
Instrument provision tool	Dental Acrylic Organizer Holder	TH04,TH04MF,TH04MFL,TH04MFS, TH04MF7	Multi-function Holder
Instrument provision tool	Dental Acrylic Organizer Holder	TH06,TH06A,TH06B	Barrier Film Dispenser
Instrument provision tool	Dental Acrylic Organizer Holder	TH07	Dental Bib Box
Instrument provision tool	Bur holder box	BF02	Root Canal Frame
Instrument provision tool	Bur holder box	BF03,BF03A,BF03B	Root Canal Measuring Table
Instrument provision tool	Bur holder box	BF04	Microdont
Instrument provision tool	Bur holder box	BF05	Root Canal Measuring Ruler
Instrument provision tool	Bur holder box	BF0517	Gutta-Percha Measuring Ruler