

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

Name und Adresse des Herstellers: **Huanghua Promisee Dental Co.,Ltd.**  
Name and address of the manufacturer: **Mould Industry Garden, Empolder Section, Huanghua 061100,  
Hebei China**

Authorized representative of the European Union: **MedNet EC-REP GmbH  
Borkstrasse 10 · 48163 Muenster · Germany  
SRN:DE-AR-000000002**

the medical device: **Group name: Impression tool  
Product name: Impression Tray  
Basic UDI-DI:69544540IMTR001WH  
Rim Former for dental use  
Basic UDI-DI: 69544540RIFO001U7  
(alternative name and type see attachment)**

of class: **Class I**  
according to Rule 5 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 harmonized standards.

EN ISO 14971: 2019	EN ISO 15223-1: 2016	EN 1041:2008+A1:2013	ISO 10993-1: 2018
EN 62366-1:2015	EN ISO 10993-5:2009	EN ISO 10993-10:2013	ISO 7405:2008
EN ISO 13485 :2016	EN1639:2009	MEDDEV 2.7/1 rev 4	MEDDEV 2.12/1 rev 8

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

*Huanghua City, 2021. 8. 23*

Ort, Datum / Place, date /

Lieu, date / Luogo, data

*He Qingxuan, General manager*

Name und Funktion / Name and function /

Nom et fonction / Nome e funzione

## Attachment

## Product Specification List

Group name	Product name	Model	Product specification
Impression tool	Impression Tray	IT01,IT0101,IT0102,IT0103,IT0104,IT0105,IT0106,IT0107,IT0108,IT0109,IT0110,IT02,IT0201,IT0202,IT0203,IT0204,IT0205,IT0206,IT0207,IT0208,IT0209,IT0210,IT05,IT07,BT,BT01,BT02,BT03,BT04,BT05	
Impression tool	Impression Tray	IT06	Holder
Impression tool	Impression Tray	TB01, TB01L, TB01M, TB01S	Tray Base
Impression tool	Impression Tray	BP01,BP02,BP03	Base Plate Wax
Impression tool	Impression Tray	BP04	Wax Rim
Impression tool	Rim Former for dental use	BP0501,BP0502	