PLASDENT
CORPORATION

Declaration of Conformity

We hereby certify that the mentioned device(s) below have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health Products (Medical Devices) Regulations. We herewith confirmed with the requirement set forth in the Council Directive on harmonization of the laws of member States concerning Medical Device Directive (93/42/EEC) as amended by Directive 2017/47/EC, and that the device is covered by the present declaration in conformity with Regulation (EU) 2017/745. We certify that the EU declaration of conformity is issued under the sole responsibility of the manufacturer per MDR Annex IV, 2.

1.1 **Product Names: Denture Box**

1.2 **Product Code: 200BTH**

1.3 **Risk Classification: Unclassified. Non-Medical Device according to the definition under Annex VIII of MDR Rule 1.**

1.4 **Manufacturer's Name & Address**: **Shengiho Enterprise Co., Ltd**.
No. 57, Guangming W. Rd., Nanshi, Vil.
Wufeng Dist., Taichung City 41358, Taiwan

1.5 **Material: Polypropylene.**

1.6 **Identification of Certificates: ISO 13485:2016 & ISO 9001:2015**

1.7 **Intended Purpose: To store denture.**

Signed: 

PLASDENT
CORPORATION
Stamp of Plasdent Corporation

Belen G. Walayat
Corporate Manager

Date: July 22, 2025