



**YAMAHACHI DENTAL MFG., CO.**

MANUFACTURERS, IMPORTERS AND  
EXPORTERS OF DENTAL PRODUCTS

54-1 OCHIGARA, NISHIURA-CHO  
GAMAGORI-CITY, AICHI-PREF., JAPAN 443-0105  
TEL: ++81-533-57-7121  
FAX: ++81-533-57-1764  
URL: <http://www.yamahachi-dental.co.jp/>  
E-mail: [box@yamahachi-dental.co.jp](mailto:box@yamahachi-dental.co.jp)

### EU Declaration of Conformity

Manufacturer YAMAHACHI DENTAL MFG., CO.  
Address 54-1 Ochigara, Nishiura-cho, Gamagori-city, Aichi-pref., 443-0105, JAPAN

European Representative Name OBELIS S.A  
Address Bd. Général Wahis, 53, 1030 Brussels, Belgium  
Tel: +32.2.732.59.54 Fax: +32.2.732.60.03 E-mail: [mail@obelis.net](mailto:mail@obelis.net)

Product Name  
• NEW ACE  
• NAPERCE  
• NEW ACE & NAPERCE COMBINATION SET  
• Crown PX  
• Efucera PX  
• CROWN PX & EFUCERA PX COMBINATION SET  
• PMMA DISK

Intended Purpose Resin teeth for denture, Acrylic resin material for CAD/CAM machine  
Products covered Production lots after October 17, 2019  
Classification Class IIa (MDD, Annex IX, Rule 5 or 8)

We herewith declare that the above-mentioned products meet the provisions of the following EC Council Directives and Standards. According to EC-Directive 93/42/EEC requirements the company applies for approval of its product through annex V, VII & IX. All supporting documents are retained under the premises of the manufacturer and the notified body.

### DIRECTIVES

**General applicable directives:** Medical Device Directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC)

**Standard:** It is in conformity with the provisions of that Directive and with our voluntary control as defined in the technical file.

**Notified body:** SGS Belgium NV

Certificate NO.: 1639

Address: Noorderlaan 87 BE-2030 Antwerpen Belgium

Tel +32(0)3 545 48 60 Fax +32(0)3 545 48 49

Signed: \_\_\_\_\_

Date: May, 13, 2021

Print Name: Akifumi Kani

Authority: Manager of QA Dept.