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

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 New York Dental Kft.
Address Frangepan utca 66/b.Budapest, 1135 Hungary
Tel ++36-1-383-3337 Fax ++36-1-220-9555

Product Name		
	NEW ACE	PMMA DISK
	NAPERCE	ZZ PMMA DISK
	CROWN NS	AG PMMA DISK
	EFUCERA NS	Basis TWIN CURE POWDER 1kg
	CROWN PX	Basis TWIN CURE LIQUID 500ml
	EFUCERA PX	

Intended Purpose Resin teeth for denture, Acrylic resin material for CAD/CAM machine, Acrylic resin material for denture base
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.: JP19/040512
Address: Noorderlaan 87 BE-2030 Antwerpen Belgium
Tel +32(0)3 545 48 60 Fax +32(0)3 545 48 49

Signed: _____ Date: January, 18, 2021

Print Name: Akifumi Kani Authority: Manager of QA Dept.

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

EU Declaration of Conformity

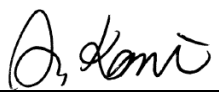
Manufacturer YAMAHACHI DENTAL MFG.,CO.
Address 54-1 Ochigara, Nishiura-cho, Gamagori-city, Aichi-pref., 443-0105, JAPAN
(SRN; JP-MF-000024849)

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
(SRN; BE-AR-000000106)

#	Commercial name/ Trade name	Model/ Reorder/ Catalogue no.#	Description	Intended Purpose	Class	Classification rule applied	BASIC UDI - DI	GMDN/ EMDN code
1	Paraffin Wax	B-07-10Y	Wax material for wax denture.	trial denture / wax denture	I	MDR, Annex VIII, Rule 5	45822756334808WX0V5	34808 Dental base plate
2	Bite Rim Stick	B-07-07Y	Wax material for wax denture.	trial denture / wax denture	I	MDR, Annex VIII, Rule 5		34808 Dental base plate
3	WAX DISK / WAX DISK α	B-07-14Y	Wax material for wax pattern.	wax pattern for casting	I	MDR, Annex VIII, Rule 5	45822756316189CW0RW	16189 Dental casting wax

Products covered Production lots after March, 16, 2022

We, YAMAHACHI DENTAL MFG.,CO. hereby declare under our sole responsibility that the above device comply with the provisions of the REGULATION (EU) 2017/745.
The devices are Class I following Rule 5 of Annex VIII of REGULATION (EU) 2017/745.
The conformity assessment procedure has been performed following Art.19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.
The following Standards have been used and in relation to which conformity is declared: ISO 15854:2021.
There are no Common Specifications that apply.

Signed:  (Aichi, JAPAN) Date: October, 26, 2022

Print Name: Akifumi Kani Authority: Manager of QA Dept.