

# 2010

Virginia Dental SC, Inc

D/B/A  
DentalPartsHäus.com



## EC Declaration of Conformity

### Council Directive 93/42/EEC concerning medical devices

We, DENTALPARTSHÄUS.COM of RICHMOND VIRGINIA OF USA

Certify that the replacement products described is in conformity with the applicable provisions of Council Directive 93/42/EEC concerning medical devices.

DENTAL ROTOR

O-Rings, Washers, Ball Bearings and related Hardwares

Perry Dan Levenson )

15.9.2011

## [CE – CERTIFICATE OF CONFORMITY]

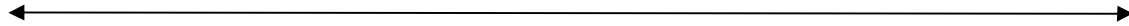
Regulations discussions and references: Requirements of CE markings of spare parts for the reconstruction and restoration of dental handpieces.

**EUROPEAN COMMISSION  
DG ENTERPRISE**

**Directorate G**

**Unit 4 - Pressure Equipment, Medical Devices, Metrology**

**MEDICAL DEVICES : Guidance document  
MEDDEV 2. 1/1  
April 1994**



GUIDELINES RELATING TO THE APPLICATION OF :  
THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES  
THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

Definition of "medical devices"  
Definition of "accessory"  
Definition of "manufacturer"

## I. FIELD OF APPLICATION – DEFINITIONS

### 1. Directive 93/42/EEC on medical devices

#### 1.1 Definition of "medical devices"

Excerpt from Page 4:

“Spare parts supplied for replacement of existing components of a device, the conformity of which has already been established, are not medical devices. If spare parts, however, change significantly the characteristics or performances of a device with regard to its already established conformity, such spare parts are to be considered as devices in their own right.”

<sup>1</sup> see MEDDEV. 5/93 rev. 2

<sup>2</sup> see MEDDEV 13/93

<sup>3</sup> see MEDDEV.10/93 rev. 1

<sup>4</sup> see MEDDEV. 1/94

---

# DECLARATION OF CONFORMITY

---



**Manufacturer :** VIRGINIA DENTAL SC INC T/A DENTALPARTSHAUS.COM

**Address :** DENTALPARTSHAUS - 1803 Lakecrest Court - Richmond, Virginia 23238 U.S.A.

## **Class I Products**

- TC 80 BC ROTOR (CARTRIDGE)
- TC 95 RM ROTOR (CARTRIDGE)
- ALEGRA TE 95 BC ROTOR (CARTRIDGE)
- SYNEA ROTOR (CARTRIDGE)
- WH GOLD WIDE BEARING (BALL BEARING)
- WH ATTACHMENT ANGULDURUVA BEARING (BALL BEARING)
- BIEN AIR BORA ROTOR (CARTRIDGE)
- BIEN AIR BLACK PEARL ROTOR (CARTRIDGE)
- BIEN AIR PRESTIGE ROTOR (CARTRIDGE)
- BIEN AIR ONDINE ROTOR (CARTRIDGE)
- BIEN AIR LARGE BEARING (BALL BEARING)
- BIEN AIR PRESTIGE / ONDINE BEARING (BALL BEARING)
- KAVO 625/625C/625D ROTOR (CARTRIDGE)
- KAVO SUPER TORQUE ROTOR (CARTRIDGE)
- KAVO 632/632DA ROTOR (CARTRIDGE)
- KAVO 633/634 ROTOR (CARTRIDGE)
- KAVO 636/646 ROTOR (CARTRIDGE)
- KAVO 639 ROTOR (CARTRIDGE)
- KAVO 630/640 ROTOR (CARTRIDGE)
- KAVO 642B/643B/645B ROTOR (CARTRIDGE)
- KAVO 647B ROTOR (CARTRIDGE)
- KAVO 640C ROTOR (CARTRIDGE)
- KAVO 649B ROTOR (CARTRIDGE)
- KAVO 650B ROTOR (CARTRIDGE)
- KAVO 655/660B/C ROTOR (CARTRIDGE)
- KAVO GentleForce 6000B ROTOR (CARTRIDGE)
- KAVO GENTLEsilence 6500B ROTOR (CARTRIDGE)
- KAVO GentleForce 7000M/B ROTOR (CARTRIDGE)
- KAVO GentleForce 8000B ROTOR (CARTRIDGE)
- KAVO 645 ROTOR (CARTRIDGE)
- KAVO GOLD BEARING (BALL BEARING)
- SIRONA T2 RACER ROTOR (CARTRIDGE)
- SIRONA T1 ROTOR (CARTRIDGE)
- SIRONA T3 ROTOR (CARTRIDGE)
- SIRONA BEARING (BALL BEARING)
- NSK SMOOTH/STRAIGHT BEARING (BALL BEARING)
- CASTELLINI ROTOR (CARTRIDGE)
- CASTELLINI BEARING (BALL BEARING)
- MK DENT ROTOR (CARTRIDGE)
- MK DENT BEARING (BALL BEARING)

**Classification :** Class I

WE HEREWITH DECLARE  
THAT THE ABOVE MENTIONED PRODUCT MEET THE PROVISION OF THE FOLLOWING  
EC COUNCIL DIRECTIVE AND STANDARDS.

### **Directive**

Council Directive **93 / 42 / EEC** of 14 June 1993 concerning medical devices ( MDD  
93/42/EEC )

---

## ***DECLARATION OF CONFORMITY***

---

### **Standards**

- *EN14971: 2001 Risk Analysis for Medical Devices*
- *EN 980: 2003 (14368) medical device labelling requirements*

VIRGINIA DENTAL SC, INC.

DATE: 27.12.2007



PERRY DAN LEVENSON