

2007

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)

27.12.2007

[CE – CERTIFICATE OF CONFORMITY]

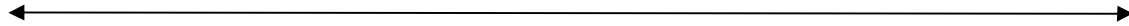
Regulations discussions and references: Requirements of CE markings of spare parts for the reconstruction and restoration of dental handpieces.

**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.”

¹ see MEDDEV. 5/93 rev. 2

² see MEDDEV 13/93

³ see MEDDEV.10/93 rev. 1

⁴ see MEDDEV. 1/94