
Legal Manufacturer:

**KaVo Dental GmbH
Bismarckring 39
88400 Biberach, Germany**

**815-1700 elements e-motion unit, US
815-1701 elements e-motion unit, EU
815-1702 elements e-motion unit, EE
815-1703 elements e-motion unit, UK
815-1704 elements e-motion unit, AUS
815-1705 elements e-motion unit, BRA
815-1706 elements e-motion unit, MEA
815-1707 elements e-motion unit, NE
815-1708 elements e-motion unit, APAC**

in connection with

**815-1711 elements e-motion Power Cable, US
815-1712 elements e-motion Power Cable, EU
815-1713 elements e-motion Power Cable, UK
815-1714 elements e-motion Power Cable, AUS
815-1715 elements e-motion Power Cable, BRA
815-1720 elements e-motion Foot Pedal
815-1722 elements e-motion Motor Cord**

93 / 42 / EEC

**Medical Devices / Annex I
Medical Devices / Annex IX - Class IIa (Rule 9)**

2011 / 65 / EC

**RoHS – On the restriction of the use of certain hazardous
substances in electrical and electronic equipment**

G

We declare in sole responsibility that the products manufactured by us to which this statement refers, conform to the essential requirements according to the above-mentioned directive. The specified standards or normative documents were applied to evaluate the product.

D

Wir erklären in alleiniger Verantwortung, dass die von uns hergestellten Produkte, auf die sich diese Erklärung bezieht, mit den grundlegenden Anforderungen gemäß den Bestimmungen der obigen Richtlinie übereinstimmen. Zur Beurteilung des Erzeugnisses wurden die benannten Normen oder normative Dokumente angewandt.

FR

Nous déclarons sous notre seule responsabilité que les produits fabriqués par nos soins, auxquels se réfère cette déclaration, sont conformes aux exigences essentielles selon les dispositions de la directive susmentionnée. Les normes ou autres documents normatifs désignés sont utilisés pour l'évaluation de ce produit.

IT

Dichiariamo sotto nostra esclusiva responsabilità che i prodotti da noi fabbricati, a cui si riferisce la presente dichiarazione, sono conformi ai requisiti fondamentali ai sensi delle disposizioni della direttiva summenzionata. Per la valutazione del prodotto sono stati applicati le norme o i documenti normativi citati.

CZ

Prohlašujeme s výhradní odpovědností, že se námi vyráběné výrobky, na které se vztahuje toto prohlášení, shodují se základními požadavky podle předpisů výše uvedené směrnice. K posouzení výrobku byly použity uvedené normy nebo normativy.

ES

Por la presente declaramos que en nuestra propia responsabilidad los productos que nosotros fabricamos, y a los que hace referencia esta declaración, cumplen los requisitos básicos de conformidad con las disposiciones de la directiva arriba mencionada. Las normas o documentos normativos mencionados se aplican en la evaluación de dichos productos.

H

Felelőségünk teljes tudatában kinyilatkoztatjuk, hogy termékeink, melyekre ez a megfelelőségi nyilatkozat vonatkozik, megfelelnek a fenn említett előírásoknak. Termékeink a fenn említett előírások és szabványok alapján lettek elbírálva.

effective date Biberach, 02.10.2019
expiry date Biberach, 26.05.2024


Klaus Michael Reisenauer
Senior Director Regulatory
Affairs/Quality Assurance

Notified Body - Dekra Certification GmbH - Handwerkstrasse 15 - D-70565 Stuttgart - ID-Number: 0124

Annex VII EC Declaration of Conformity

Manufacturer Name and Address: Kerr Corporation also trading as Pentron Clinical
1717 West Collins Avenue
Orange, California 92867 USA

Authorized Representative Name and Address: Kerr Italia S.r.l.,
Via Passanti, 174
84018 Scafati, (SA), Italy

Technical File Name/Number: Horizen NS (ZenFlex) Files
Endo-016

Product Tradename(s): ZenFlex Files

Device Identification: see Attachment 1

Classification and Rule(s): Class IIa, Rule 6

Notified Body: BSI Group The Netherlands B.V.
Notified Body Number: 2797
Conformity Assessment Procedure & Certificate Issued: Annex V, CE certificate 00847

Declaration Statement:

We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

21 May 2021

Issue date



Name: Mark Dzendzel

Title: Director, Quality Assurance Systems



Horizen NS (ZenFlex) Files, Endo-016 - Attachment 1 to Annex VII EC Declaration of Conformity			
REF	Description		
818-1206	.20/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1207	.20/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1208	.20/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1256	.25/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1257	.25/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1258	.25/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1306	.30/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1307	.30/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1308	.30/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1356	.35/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1357	.35/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1358	.35/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1406	.40/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1407	.40/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1408	.40/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1456	.45/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1457	.45/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1458	.45/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1506	.50/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1507	.50/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1508	.50/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1556	.55/.04/21mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1557	.55/.04/25mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1558	.55/.04/31mm	ZenFlex - ROTARY NICKEL TITANIUM	EU/ROW
818-1421	ZenFlex .04/21mm ASSORTED PACK EU/ROW		
818-1425	ZenFlex .04/25mm ASSORTED PACK EU/ROW		
818-2206	.20/.06/21mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2207	.20/.06/25mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2208	.20/.06/31mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2256	.25/.06/21mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2257	.25/.06/25mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2258	.25/.06/31mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2306	.30/.06/21mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2307	.30/.06/25mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2308	.30/.06/31mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2356	.35/.06/21mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
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818-2458	.45/.06/31mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2506	.50/.06/21mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
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818-2557	.55/.06/25mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW
818-2558	.55/.06/31mm	ZenFlex - ROTARY NICKEL TITANIUM FILE	EU/ROW



Horizen NS (ZenFlex) Files, Endo-016 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
818-1621	ZenFlex .06/21mm ASSORTED PACK EU/ROW
818-1625	ZenFlex .06/25mm ASSORTED PACK EU/ROW