

## 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
818-2357	.35/.06/25mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2358	.35/.06/31mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2406	.40/.06/21mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2407	.40/.06/25mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2408	.40/.06/31mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2456	.45/.06/21mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2457	.45/.06/25mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2458	.45/.06/31mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2506	.50/.06/21mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2507	.50/.06/25mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2508	.50/.06/31mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
818-2556	.55/.06/21mm ZenFlex - ROTARY NICKEL TITANIUM FILE EU/ROW
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