

Annex VII EC Declaration of Conformity

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

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

Technical File Name/Number: Endodontic Hand Files/Endo-007

Product Tradename(s): K-File, K-Flex, Triple-Flex, Hedstrom, Reamers

Device Identification: see Attachment 1

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

Notified Body: BSI Group The Netherlands B.V.
Notified Body Number: 2797

Conformity Assessment Procedure & Certificate Issued: Annex IX
CE Certificate 00847

Declaration Statement:

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

Regulatory Affairs Signature:



12 March 2021

Issue date

Name: Mark Dzendzel

Title: Director, Quality Assurance Systems

Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
12766	Hedstrom, 21mm Size 15, 6-Pack
12769	Hedstrom, 21mm Size 20, 6-Pack
12772	Hedstrom, 21mm Size 25, 6-Pack
12775	Hedstrom, 21mm Size 30, 6-Pack
12778	Hedstrom, 21mm Size 35, 6-Pack
12781	Hedstrom, 21mm Size 40, 6-Pack
12784	Hedstrom, 21mm Size 45, 6-Pack
12787	Hedstrom, 21mm Size 50, 6-Pack
12790	Hedstrom, 21mm Size 55, 6-Pack
12793	Hedstrom, 21mm Size 60, 6-Pack
12796	Hedstrom, 21mm Size 70, 6-Pack
11344	Hedstrom, 25mm Size 15, 6-Pack
11345	Hedstrom, 25mm Size 20, 6-Pack
11346	Hedstrom, 25mm Size 25, 6-Pack
11347	Hedstrom, 25mm Size 30, 6-Pack
11348	Hedstrom, 25mm Size 35, 6-Pack
11349	Hedstrom, 25mm Size 40, 6-Pack
11350	Hedstrom, 25mm Size 45, 6-Pack
11351	Hedstrom, 25mm Size 50, 6-Pack
11352	Hedstrom, 25mm Size 55, 6-Pack
11353	Hedstrom, 25mm Size 60, 6-Pack
11354	Hedstrom, 25mm Size 70, 6-Pack
12814	Hedstrom, 30mm Size 15, 6-Pack
12817	Hedstrom, 30mm Size 20, 6-Pack
12820	Hedstrom, 30mm Size 25, 6-Pack
12823	Hedstrom, 30mm Size 30, 6-Pack
12826	Hedstrom, 30mm Size 35, 6-Pack
12829	Hedstrom, 30mm Size 40, 6-Pack
12832	Hedstrom, 30mm Size 45, 6-Pack
12835	Hedstrom, 30mm Size 50, 6-Pack
12838	Hedstrom, 30mm Size 55, 6-Pack
12841	Hedstrom, 30mm Size 60, 6-Pack
13278	Hedstrom, 30mm Size 70, 6-Pack
12809	Hedstrom, 21mm Asst 15/40, 6-Pack
12810	Hedstrom, 21mm Asst 45/80, 6-Pack
11359	Hedstrom, 25mm Asst 15/40, 6-Pack
11360	Hedstrom, 25mm Asst 45/80, 6-Pack
13291	Hedstrom, 30mm Asst 15/40, 6-Pack
13292	Hedstrom, 30mm Asst 45/80, 6-Pack
61684	Hedstrom, 21mm Size 80, 6-Pack
61702	Hedstrom, 25mm Size 80, 6-Pack
61720	Hedstrom, 30mm Size 80, 6-Pack

Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
14127	K-File, 21mm Size 08, 6-Pack
06003	K-File, 21mm Size 10, 6-Pack
06004	K-File, 21mm Size 15, 6-Pack
06005	K-File, 21mm Size 20, 6-Pack
06014	K-File, 21mm Size 25, 6-Pack
06015	K-File, 21mm Size 30, 6-Pack
06016	K-File, 21mm Size 35, 6-Pack
06019	K-File, 21mm Size 40, 6-Pack
06020	K-File, 21mm Size 45, 6-Pack
06021	K-File, 21mm Size 50, 6-Pack
06022	K-File, 21mm Size 55, 6-Pack
06023	K-File, 21mm Size 60, 6-Pack
06024	K-File, 21mm Size 70, 6-Pack
06026	K-File, 21mm Size 80, 6-Pack
61356	K-File, 21mm 14-40 Asst.
61363	K-File, 21mm Asst. 45-70 PK-6
821-8021	K-File, 21mm Asst 15/40, 6-Pack
821-8121	K-File, 21mm Asst 45/80, 6-Pack
14128	K-File, 25mm Size 08, 6-Pack
06062	K-File, 25mm Size 10, 6-Pack
06063	K-File, 25mm Size 15, 6-Pack
06064	K-File, 25mm Size 20, 6-Pack
06065	K-File, 25mm Size 25, 6-Pack
06066	K-File, 25mm Size 30, 6-Pack
06067	K-File, 25mm Size 35, 6-Pack
06069	K-File, 25mm Size 40, 6-Pack
06074	K-File, 25mm Size 45, 6-Pack
06075	K-File, 25mm Size 50, 6-Pack
06076	K-File, 25mm Size 55, 6-Pack
06077	K-File, 25mm Size 60, 6-Pack
06085	K-File, 25mm Size 70, 6-Pack
06099	K-File, 25mm Size 80, 6-Pack
61388	K-File, 25mm 15-40 Asst.
61395	K-File, 25mm 40-70 Asst.
821-8025	K-File, 25mm Asst 15/40, 6-Pack
821-8125	K-File, 25mm Asst 45/80, 6-Pack
14129	K-File, 30mm Size 08, 6-Pack
06151	K-File, 30mm Size 10, 6-Pack
06152	K-File, 30mm Size 15, 6-Pack
06153	K-File, 30mm Size 20, 6-Pack
06155	K-File, 30mm Size 25, 6-Pack
06156	K-File, 30mm Size 30, 6-Pack
06157	K-File, 30mm Size 35, 6-Pack
06159	K-File, 30mm Size 40, 6-Pack
06160	K-File, 30mm Size 45, 6-Pack
06161	K-File, 30mm Size 50, 6-Pack
06162	K-File, 30mm Size 55, 6-Pack
06163	K-File, 30mm Size 60, 6-Pack
06166	K-File, 30mm Size 70, 6-Pack
06170	K-File, 30mm Size 80, 6-Pack



Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
61420	K-File, 30mm 10-35 Asst.
61427	K-File, 30mm 45-80 Asst.
821-8030	K-File, 30mm Asst 15/40, 6-Pack
821-8130	K-File, 30mm Asst 45/80, 6-Pack
62249	K-File, 21mm Size 06, 6-Pack
62250	K-File, 25mm Size 06, 6-Pack
62251	K-File, 30mm Size 06, 6-Pack

Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
15302	K-Flex File, 21mm Size 20, 6-Pack
15306	K-Flex File, 21mm Size 25, 6-Pack
15310	K-Flex File, 21mm Size 30, 6-Pack
15314	K-Flex File, 21mm Size 35, 6-Pack
15318	K-Flex File, 21mm Size 40, 6-Pack
15322	K-Flex File, 21mm Size 45, 6-Pack
15326	K-Flex File, 21mm Size 50, 6-Pack
15330	K-Flex File, 21mm Size 55, 6-Pack
15334	K-Flex File, 21mm Size 60, 6-Pack
15122	K-Flex File, 25mm Size 08, 6-Pack
15126	K-Flex File, 25mm Size 10, 6-Pack
15130	K-Flex File, 25mm Size 15, 6-Pack
15134	K-Flex File, 25mm Size 20, 6-Pack
15138	K-Flex File, 25mm Size 25, 6-Pack
15142	K-Flex File, 25mm Size 30, 6-Pack
15146	K-Flex File, 25mm Size 35, 6-Pack
15150	K-Flex File, 25mm Size 40, 6-Pack
15154	K-Flex File, 25mm Size 45, 6-Pack
15158	K-Flex File, 25mm Size 50, 6-Pack
15162	K-Flex File, 25mm Size 55, 6-Pack
15166	K-Flex File, 25mm Size 60, 6-Pack
15170	K-Flex File, 25mm Size 70, 6-Pack
15174	K-Flex File, 25mm Size 80, 6-Pack
15178	K-Flex File, 25mm Size 90, 6-pack
15182	K-Flex File, 25mm Size 100, 6-pack
15206	K-Flex File, 30mm Size 08, 6-Pack
15210	K-Flex File, 30mm Size 10, 6-Pack
15214	K-Flex File, 30mm Size 15, 6-Pack
15218	K-Flex File, 30mm Size 20, 6-Pack
15222	K-Flex File, 30mm Size 25, 6-Pack
15226	K-Flex File, 30mm Size 30, 6-Pack
15230	K-Flex File, 30mm Size 35, 6-Pack
15234	K-Flex File, 30mm Size 40, 6-Pack
15238	K-Flex File, 30mm Size 45, 6-Pack
15242	K-Flex File, 30mm Size 50, 6-Pack
15246	K-Flex File, 30mm Size 55, 6-Pack
15250	K-Flex File, 30mm Size 60, 6-Pack
15254	K-Flex File, 30mm Size 70, 6-Pack
15258	K-Flex File, 30mm Size 80, 6-Pack
60120	K-Flex File, 21mm Size 06, 6-Pack
60125	K-FLEX NO. 25 21MM
60141	K-FLEX FILES 21MM SZ 15-40 ASST. PK/6
60142	K-FLEX FILES 21MM SZ 45-60 ASST. PK/6
60144	K-Flex File, 25mm Size 06, 6-Pack
60165	K-FLEX FILES 25MM SZ 15-40 ASST. PK/6
60166	K-FLEX FILES 25MM SZ 45-80 ASST. PK/6
60167	K-FLEX FILES 25MM SZ 80-100 ASST. PK/6
60189	K-FLEX FILES 30MM SZ 15-40 ASST. PK/6

Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
60190	K-FLEX FILES 30MM SZ 45-80 ASST. PK/6
60191	K-FLEX FILES 30MM SZ 80-100 ASST.PK/6
60193	K-Flex File, 30mm Size 06, 6-Pack
821-4021	K-Flex File, 21mm Asst 15/40, 6-Pack
821-4025	K-Flex File, 25mm Asst 15/40, 6-Pack
821-4125	K-Flex File, 25mm Asst 45/80, 6-Pack
821-4030	K-Flex File, 30mm Asst 15/40, 6-Pack
821-4130	K-Flex File, 30mm Asst 45/80, 6-Pack
15290	K-Flex File, 21mm Size 08, 6-Pack
15294	K-Flex File, 21mm Size 10, 6-Pack
15298	K-Flex File, 21mm Size 15, 6-Pack

Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
25927	Triple-Flex File, 21mm Size 08, 6-pack
25928	Triple-Flex File, 21mm Size 10, 6-pack
25929	Triple-Flex File, 21mm Size 15, 6-pack
25930	Triple-Flex File, 21mm Size 20, 6-pack
25931	Triple-Flex File, 21mm Size 25, 6-pack
25932	Triple-Flex File, 21mm Size 30, 6-pack
25933	Triple-Flex File, 21mm Size 35, 6-pack
25935	Triple-Flex File, 21mm Size 40, 6-pack
25936	Triple-Flex File, 21mm Size 45, 6-pack
25937	Triple-Flex File, 21mm Size 50, 6-pack
25938	Triple-Flex File, 21mm Size 55, 6-pack
25939	Triple-Flex File, 21mm Size 60, 6-pack
25940	Triple-Flex File, 21mm Size 70, 6-pack
25941	Triple-Flex File, 21mm Size 80, 6-pack
25943	Triple-Flex File, 25mm Size 08, 6-pack
25944	Triple-Flex File, 25mm Size 10, 6-pack
25945	Triple-Flex File, 25mm Size 15, 6-pack
25946	Triple-Flex File, 25mm Size 20, 6-pack
25947	Triple-Flex File, 25mm Size 25, 6-pack
25948	Triple-Flex File, 25mm Size 30, 6-pack
25949	Triple-Flex File, 25mm Size 35, 6-pack
25951	Triple-Flex File, 25mm Size 40, 6-pack
25952	Triple-Flex File, 25mm Size 45, 6-pack
25953	Triple-Flex File, 25mm Size 50, 6-pack
25954	Triple-Flex File, 25mm Size 55, 6-pack
25955	Triple-Flex File, 25mm Size 60, 6-pack
25956	Triple-Flex File, 25mm Size 70, 6-pack
25957	Triple-Flex File, 25mm Size 80, 6-pack
25959	Triple-Flex File, 30mm Size 08, 6-pack
25960	Triple-Flex File, 30mm Size 10, 6-pack
25961	Triple-Flex File, 30mm Size 15, 6-pack
25962	Triple-Flex File, 30mm Size 20, 6-pack
25963	Triple-Flex File, 30mm Size 25, 6-pack
25964	Triple-Flex File, 30mm Size 30, 6-pack
25965	Triple-Flex File, 30mm Size 35, 6-pack
25967	Triple-Flex File, 30mm Size 40, 6-pack
25968	Triple-Flex File, 30mm Size 45, 6-pack
25969	Triple-Flex File, 30mm Size 50, 6-pack
25970	Triple-Flex File, 30mm Size 55, 6-pack
25971	Triple-Flex File, 30mm Size 60, 6-pack
25972	Triple-Flex File, 30mm Size 70, 6-pack
25973	Triple-Flex File, 30mm Size 80, 6-pack
821-3021	Triple-Flex File, 21mm Asst 15/40, 6-pack
821-3025	Triple-Flex File, 25mm Asst 15/40, 6-pack
821-3030	Triple-Flex File, 30mm Asst 15/40, 6-pack
821-3121	Triple-Flex File, 21mm Asst 45/80, 6-pack
821-3125	Triple-Flex File, 25mm Asst 45/80, 6-pack
821-3130	Triple-Flex File, 30mm Asst 45/80, 6-pack

Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
14133	Reamer, 21mm Size 08, 6-pack
06029	Reamer, 21mm Size 10, 6-pack
06030	Reamer, 21mm Size 15, 6-pack
06031	Reamer, 21mm Size 20, 6-pack
06032	Reamer, 21mm Size 25, 6-pack
06033	Reamer, 21mm Size 30, 6-pack
06034	Reamer, 21mm Size 35, 6-pack
06038	Reamer, 21mm Size 40, 6-pack
06040	Reamer, 21mm Size 45, 6-pack
14134	Reamer, 25mm Size 08, 6-pack
06110	Reamer, 25mm Size 10, 6-pack
06111	Reamer, 25mm Size 15, 6-pack
06112	Reamer, 25mm Size 20, 6-pack
06120	Reamer, 25mm Size 25, 6-pack
06126	Reamer, 25mm Size 30, 6-pack
06127	Reamer, 25mm Size 35, 6-pack
06131	Reamer, 25mm Size 40, 6-pack
06132	Reamer, 25mm Size 45, 6-pack
821-2021	Reamer, 21mm Asst 15/40, 6-Pack
821-2025	Reamer, 25mm Asst 15/40, 6-Pack
61375	Reamer, 21mm Size 50, 6-pack
61376	Reamer, 21mm Size 55, 6-pack
61377	Reamer, 21mm Size 60, 6-pack
61378	Reamer, 21mm Size 70, 6-pack
61379	Reamer, 21mm Asst 45/70, 6-pack
61407	Reamer, 25mm Size 50, 6-pack
61408	Reamer, 25mm Size 55, 6-pack
61409	Reamer, 25mm Size 60, 6-pack
61410	Reamer, 25mm Size 70, 6-pack
61411	Reamer, 25mm Asst 45/80, 6-pack
61412	Reamer, 25mm Size 80, 6-pack
61430	Reamer, 30mm Size 10, 6-pack
61431	Reamer, 30mm Size 15, 6-pack
61432	Reamer, 30mm Size 20, 6-pack
61433	Reamer, 30mm Size 25, 6-pack
61434	Reamer, 30mm Size 30, 6-pack
61435	Reamer, 30mm Size 35, 6-pack
61436	Reamer, 30mm Asst 15/40, 6-pack
61437	Reamer, 30mm Size 40, 6-pack
61438	Reamer, 30mm Size 45, 6-pack
61439	Reamer, 30mm Size 50, 6-pack
61440	Reamer, 30mm Size 55, 6-pack
61441	Reamer, 30mm Size 60, 6-pack
61442	Reamer, 30mm Size 70, 6-pack
61443	Reamer, 30mm Asst 45/80, 6-pack
61444	Reamer, 30mm Size 80, 6-pack
62260	Reamer, 30mm Size 08, 6-pack
61372	Reamer, 21mm Asst 15/40, 6-pack
61404	Reamer, 25mm Asst 15/40, 6-pack
62252	Reamer, 21mm Size 06, 6-pack



Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
62253	Reamer, 25mm Size 06, 6-pack
62254	Reamer, 30mm Size 06, 6-pack
62260	Reamer, 30mm Size 08, 6-pack