

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: K3 Files, K3XF Files & Quantec Files
Endo-011

Product Tradename(s): K3 Files, K3XF Files & Quantec 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 July 2021

Issue date



Name: Mark Dzendzel

Title: Director, Quality Assurance Systems



K3 Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
825-2021	K3 ENG FILE .02 21MM ASSORTED PK
825-2025	K3 ENG FILE .02 25MM ASSORTED PK
825-2150	K3 ENG FILE .15/.02 30MM
825-2151	K3 ENG FILE .15/.02 21MM
825-2155	K3 ENG FILE .15/.02 25MM
825-2200	K3 ENG FILE .20/.02 30MM
825-2201	K3 ENG FILE .20/.02 21MM
825-2205	K3 ENG FILE .20/.02 25MM
825-2250	K3 ENG FILE .25/.02 30MM
825-2251	K3 ENG FILE .25/.02 21MM
825-2255	K3 ENG FILE .25/.02 25MM
825-2300	K3 ENG FILE .30/.02 30MM
825-2301	K3 ENG FILE .30/.02 21MM
825-2305	K3 ENG FILE .30/.02 25MM
825-2350	K3 ENG FILE .35/.02 30MM
825-2351	K3 ENG FILE .35/.02 21MM
825-2355	K3 ENG FILE .35/.02 25MM
825-2400	K3 ENG FILE .40/.02 30MM
825-2401	K3 ENG FILE .40/.02 21MM
825-2405	K3 ENG FILE .40/.02 25MM
825-2450	K3 ENG FILE .45/.02 30MM
825-2451	K3 ENG FILE .45/.02 21MM
825-2455	K3 ENG FILE .45/.02 25MM
825-4021	K3 ENG FILE .04 21MM ASSORTED PK
825-4025	K3 ENG FILE .04 25MM ASSORTED PK
825-4150	K3 ENG FILE .15/.04 30MM
825-4151	K3 ENG FILE .15/.04 21MM
825-4155	K3 ENG FILE .15/.04 25MM
825-4200	K3 ENG FILE .20/.04 30MM
825-4201	K3 ENG FILE .20/.04 21MM
825-4205	K3 ENG FILE .20/.04 25MM
825-4250	K3 ENG FILE .25/.04 30MM
825-4251	K3 ENG FILE .25/.04 21MM
825-4255	K3 ENG FILE .25/.04 25MM
825-4300	K3 ENG FILE .30/.04 30MM
825-4301	K3 ENG FILE .30/.04 21MM
825-4305	K3 ENG FILE .30/.04 25MM
825-4350	K3 ENG FILE .35/.04 30MM
825-4351	K3 ENG FILE .35/.04 21MM
825-4355	K3 ENG FILE .35/.04 25MM
825-4400	K3 ENG FILE .40/.04 30MM
825-4401	K3 ENG FILE .40/.04 21MM
825-4405	K3 ENG FILE .40/.04 25MM
825-4450	K3 ENG FILE .45/.04 30MM
825-4451	K3 ENG FILE .45/.04 21MM
825-4455	K3 ENG FILE .45/.04 25MM
825-4500	K3 ENG FILE .50/.04 30MM
825-4501	K3 ENG FILE .50/.04 21MM



K3 Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
825-4505	K3 ENG FILE .50/.04 25MM
825-4550	K3 ENG FILE .55/.04 30MM
825-4551	K3 ENG FILE .55/.04 21MM
825-4555	K3 ENG FILE .55/.04 25MM
825-4600	K3 ENG FILE .60/.04 30MM
825-4601	K3 ENG FILE .60/.04 21MM
825-4605	K3 ENG FILE .60/.04 25MM
825-6021	K3 ENG FILE .06 21MM ASSORTED PK
825-6025	K3 ENG FILE .06 25MM ASSORTED PK
825-6150	K3 ENG FILE .15/.06 30MM
825-6151	K3 ENG FILE .15/.06 21MM
825-6155	K3 ENG FILE .15/.06 25MM
825-6200	K3 ENG FILE .20/.06 30MM
825-6201	K3 ENG FILE .20/.06 21MM
825-6205	K3 ENG FILE .20/.06 25MM
825-6250	K3 ENG FILE .25/.06 30MM
825-6251	K3 ENG FILE .25/.06 21MM
825-6255	K3 ENG FILE .25/.06 25MM
825-6300	K3 ENG FILE .30/.06 30MM
825-6301	K3 ENG FILE .30/.06 21MM
825-6305	K3 ENG FILE .30/.06 25MM
825-6350	K3 ENG FILE .35/.06 30MM
825-6351	K3 ENG FILE .35/.06 21MM
825-6355	K3 ENG FILE .35/.06 25MM
825-6400	K3 ENG FILE .40/.06 30MM
825-6401	K3 ENG FILE .40/.06 21MM
825-6405	K3 ENG FILE .40/.06 25MM
825-6450	K3 ENG FILE .45/.06 30MM
825-6451	K3 ENG FILE .45/.06 21MM
825-6455	K3 ENG FILE .45/.06 25MM
825-6500	K3 ENG FILE .50/.06 30MM
825-6501	K3 ENG FILE .50/.06 21MM
825-6505	K3 ENG FILE .50/.06 25MM
825-6550	K3 ENG FILE .55/.06 30MM
825-6551	K3 ENG FILE .55/.06 21MM
825-6555	K3 ENG FILE .55/.06 25MM
825-6600	K3 ENG FILE .60/.06 30MM
825-6601	K3 ENG FILE .60/.06 21MM
825-6605	K3 ENG FILE .60/.06 25MM
830-0251	K3 ENG FILE .25/.10 21MM
830-0255	K3 ENG FILE .25/.10 25MM
830-0257	K3 ENG FILE .25/.10 17MM
830-0421	K3 ENG FILE .04 21MM PROCEDURE PK
830-0425	K3 ENG FILE .04 25MM PROCEDURE PK
830-0621	K3 ENG FILE .06 21MM PROCEDURE PK
830-0625	K3 ENG FILE .06 25MM PROCEDURE PK
830-2251	K3 ENG FILE .25/.12 21MM
830-2255	K3 ENG FILE .25/.12 25MM
830-2257	K3 ENG FILE .25/.12 17MM
830-7721	K3 VTVT 21MM ASSORTED PK



K3 Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
830-7725	K3 VTVT 25MM ASSORTED PK
830-8251	K3 ENG FILE .25/.08 21MM
830-8255	K3 ENG FILE .25/.08 25MM
830-8257	K3 ENG FILE .25/.08 17MM
830-9921	K-3 ENGINE FILE, G-PACK, 21MM
830-9925	K-3 ENGINE FILE, G-PACK, 25MM



K3XF Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
823-0250	K3 XF FILE .25/.10 30MM
823-0251	K3 XF FILE .25/.10 21MM
823-0255	K3 XF FILE .25/.10 25MM
823-0257	K3 XF FILE .25/.10 17MM
823-4200	K3 XF FILE .20/.04 30MM
823-4201	K3 XF FILE .20/.04 21MM
823-4205	K3 XF FILE .20/.04 25MM
823-4250	K3 XF FILE .25/.04 30MM
823-4251	K3 XF FILE .25/.04 21MM
823-4255	K3 XF FILE .25/.04 25MM
823-4300	K3 XF FILE .30/.04 30MM
823-4301	K3 XF FILE .30/.04 21MM
823-4305	K3 XF FILE .30/.04 25MM
823-4350	K3 XF FILE .35/.04 30MM
823-4351	K3 XF FILE .35/.04 21MM
823-4355	K3 XF FILE .35/.04 25MM
823-4400	K3 XF FILE .40/.04 30MM
823-4401	K3 XF FILE .40/.04 21MM
823-4405	K3 XF FILE .40/.04 25MM
823-4450	K3 XF FILE .45/.04 30MM
823-4451	K3 XF FILE .45/.04 21MM
823-4455	K3 XF FILE .45/.04 25MM
823-4500	K3 XF FILE .50/.04 30MM
823-4501	K3 XF FILE .50/.04 21MM
823-4505	K3 XF FILE .50/.04 25MM
823-6200	K3 XF FILE .20/.06 30MM
823-6201	K3 XF FILE .20/.06 21MM
823-6205	K3 XF FILE .20/.06 25MM
823-6250	K3 XF FILE .25/.06 30MM
823-6251	K3 XF FILE .25/.06 21MM
823-6255	K3 XF FILE .25/.06 25MM
823-6300	K3 XF FILE .30/.06 30MM
823-6301	K3 XF FILE .30/.06 21MM
823-6305	K3 XF FILE .30/.06 25MM
823-6350	K3 XF FILE .35/.06 30MM
823-6351	K3 XF FILE .35/.06 21MM
823-6355	K3 XF FILE .35/.06 25MM
823-6400	K3 XF FILE .40/.06 30MM
823-6401	K3 XF FILE .40/.06 21MM
823-6405	K3 XF FILE .40/.06 25MM
823-6450	K3 XF FILE .45/.06 30MM
823-6451	K3 XF FILE .45/.06 21MM
823-6455	K3 XF FILE .45/.06 25MM
823-6500	K3 XF FILE .50/.06 30MM
823-6501	K3 XF FILE .50/.06 21MM
823-6505	K3 XF FILE .50/.06 25MM
823-8250	K3 XF FILE .25/.08 30MM
823-8251	K3 XF FILE .25/.08 21MM
823-8255	K3 XF FILE .25/.08 25MM



K3XF Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
823-8257	K3 XF FILE .25/.08 17MM
823-4550	K3 XF FILE .55/.04 30MM
823-4551	K3 XF FILE .55/.04 21MM
823-4555	K3 XF FILE .55/.04 25MM
823-4600	K3 XF FILE .60/.04 30MM
823-4601	K3 XF FILE .60/.04 21MM
823-4605	K3 XF FILE .60/.04 25MM
823-6550	K3 XF FILE .55/.06 30MM
823-6551	K3 XF FILE .55/.06 21MM
823-6555	K3 XF FILE .55/.06 25MM
823-6600	K3 XF FILE .60/.06 30MM
823-6601	K3 XF FILE .60/.06 21MM
823-6605	K3 XF FILE .60/.06 25MM
823-8201	K3 XF FILE .20/.08 21MM
823-8205	K3 XF FILE .20/.08 25MM
823-8207	K3 XF FILE .20/.08 17MM
823-8200	K3 XF FILE .20/.08 30MM
823-8301	K3 XF FILE .30/.08 21MM
823-8305	K3 XF FILE .30/.08 25MM
823-8307	K3 XF FILE .30/.08 17MM
823-8300	K3 XF FILE .30/.08 30MM
823-8401	K3 XF FILE .40/.08 21MM
823-8405	K3 XF FILE .40/.08 25MM
823-8407	K3 XF FILE .40/.08 17MM
823-8400	K3 XF FILE .40/.08 30MM
823-0201	K3 XF FILE .20/.10 21MM
823-0205	K3 XF FILE .20/.10 25MM
823-0207	K3 XF FILE .20/.10 17MM
823-0200	K3 XF FILE .20/.10 30MM
823-0301	K3 XF FILE .30/.10 21MM
823-0305	K3 XF FILE .30/.10 25MM
823-0307	K3 XF FILE .30/.10 17MM
823-0300	K3 XF FILE .30/.10 30MM
823-0401	K3 XF FILE .40/.10 21MM
823-0405	K3 XF FILE .40/.10 25MM
823-0407	K3 XF FILE .40/.10 17MM
823-0400	K3 XF FILE .40/.10 30MM
823-2201	K3 XF FILE .20/.12 21MM
823-2205	K3 XF FILE .20/.12 25MM
823-2207	K3 XF FILE .20/.12 17MM
823-2200	K3 XF FILE .20/.12 30MM
823-2301	K3 XF FILE .30/.12 21MM
823-2305	K3 XF FILE .30/.12 25MM
823-2307	K3 XF FILE .30/.12 17MM
823-2300	K3 XF FILE .30/.12 30MM
823-2401	K3 XF FILE .40/.12 21MM
823-2405	K3 XF FILE .40/.12 25MM
823-2407	K3 XF FILE .40/.12 17MM
823-2400	K3 XF FILE .40/.12 30MM
823-4150	K3 XF FILE .15/.04 30MM



K3XF Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
823-4151	K3 XF FILE .15/.04 21MM
823-4155	K3 XF FILE .15/.04 25MM
823-6150	K3 XF FILE .15/.06 30MM
823-6151	K3 XF FILE .15/.06 21MM
823-6155	K3 XF FILE .15/.06 25MM
823-2257	K3 XF FILE .25/.12 17MM
823-2251	K3 XF FILE .25/.12 21MM
823-0621	K3 XF FILE PROCEDURE PACK .06/21MM
823-0625	K3 XF FILE PROCEDURE PACK .06/25MM
823-0421	K3 XF FILE PROCEDURE PACK .04/21MM
823-0425	K3 XF FILE PROCEDURE PACK .04/25MM
823-4021	K3 XF FILE 15-40 ASST .04/21MM
823-4025	K3 XF FILE 15-40 ASST .04/25MM
823-6021	K3 XF FILE 15-40 ASST .06/21MM
823-6025	K3 XF FILE 15-40 ASST .06/25MM
823-9921	K3 XF FILE G-PACK 21MM
823-9925	K3 XF FILE G-PACK 25MM



Quantec Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
815-2000	QUANTEC AXXESS ENG SC 25-3 /.03 21MM #5
815-2001	QUANTEC AXXESS ENG SC 25-3 /.03 25MM #5
815-2002	QUANTEC AXXESS ENG SC 25-4 /.04 21MM #6
815-2003	QUANTEC AXXESS ENG SC 25-4 /.04 25MM #6
815-2004	QUANTEC AXXESS ENG SC 25-5 /.05 21MM #7
815-2005	QUANTEC AXXESS ENG SC 25-5 /.05 25MM #7
815-2006	QUANTEC AXXESS ENG SC 25-6 /.06 21MM #8
815-2007	QUANTEC AXXESS ENG SC 25-6 /.06 25MM #8
815-2008	QUANTEC AXXESS ENG SC 15 /.02 21MM #2
815-2009	QUANTEC AXXESS ENG SC 15 /.02 25MM #2
815-2010	QUANTEC AXXESS ENG SC 20 /.02 21MM #3
815-2011	QUANTEC AXXESS ENG SC 20 /.02 25MM #3
815-2012	QUANTEC AXXESS ENG SC 25 /.02 21MM #4
815-2013	QUANTEC AXXESS ENG SC 25 /.02 25MM #4
815-2014	QUANTEC AXXESS ENG SC 30 /.02 21MM
815-2015	QUANTEC AXXESS ENG SC 30 /.02 25MM
815-2016	QUANTEC AXXESS ENG SC 35 /.02 21MM
815-2017	QUANTEC AXXESS ENG SC 35 /.02 25MM
815-2018	QUANTEC AXXESS ENG SC 40 /.02 21MM #9
815-2019	QUANTEC AXXESS ENG SC 40 /.02 25MM #9
815-2020	QUANTEC AXXESS ENG SC 45 /.02 21MM #10
815-2021	QUANTEC AXXESS ENG SC 45 /.02 25MM #10
815-2022	QUANTEC AXXESS ENG SC 50 /.02 21MM
815-2023	QUANTEC AXXESS ENG SC 50 /.02 25MM
815-2024	QUANTEC AXXESS ENG SC 55 /.02 21MM
815-2025	QUANTEC AXXESS ENG SC 55 /.02 25MM
815-2026	QUANTEC AXXESS ENG SC 60 /.02 21MM
815-2027	QUANTEC AXXESS ENG SC 60 /.02 25MM
815-2028	QUANTEC AXXESS ENG SC 25-6 /.06 17MM #1
815-2100	QUANTEC AXXESS ENG LX 25-3/.03 21MM #5
815-2101	QUANTEC AXXESS ENG LX 25-3/.03 25MM #5
815-2102	QUANTEC AXXESS ENG LX 25-4/.04 21MM #6
815-2103	QUANTEC AXXESS ENG LX 25-4/.04 25MM #6
815-2104	QUANTEC AXXESS ENG LX 25-5/.05 21MM #7
815-2105	QUANTEC AXXESS ENG LX 25-5/.05 25MM #7
815-2106	QUANTEC AXXESS ENG LX 25-6/.06 21MM #8
815-2107	QUANTEC AXXESS ENG LX 25-6/.06 25MM #8
815-2108	QUANTEC AXXESS ENG LX 15 /.02 21MM #2
815-2109	QUANTEC AXXESS ENG LX 15 /.02 25MM #2
815-2110	QUANTEC AXXESS ENG LX 20 /.02 21MM #3
815-2111	QUANTEC AXXESS ENG LX 20 /.02 25MM #3
815-2112	QUANTEC AXXESS ENG LX 25 /.02 21MM #4
815-2113	QUANTEC AXXESS ENG LX 25 /.02 25MM #4
815-2114	QUANTEC AXXESS ENG LX 30 /.02 21MM
815-2115	QUANTEC AXXESS ENG LX 30 /.02 25MM
815-2116	QUANTEC AXXESS ENG LX 35 /.02 21MM
815-2117	QUANTEC AXXESS ENG LX 35 /.02 25MM
815-2118	QUANTEC AXXESS ENG LX 40 /.02 21MM #9



Quantec Files - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
815-2119	QUANTEC AXXESS ENG LX 40 /.02 25MM #9
815-2120	QUANTEC AXXESS ENG LX 45 /.02 21MM #10
815-2121	QUANTEC AXXESS ENG LX 45 /.02 25MM #10
815-2122	QUANTEC AXXESS ENG LX 50 /.02 21MM
815-2123	QUANTEC AXXESS ENG LX 50 /.02 25MM
815-2124	QUANTEC AXXESS ENG LX 55 /.02 21MM
815-2125	QUANTEC AXXESS ENG LX 55 /.02 25MM
815-2126	QUANTEC AXXESS ENG LX 60 /.02 21MM
815-2127	QUANTEC AXXESS ENG LX 60 /.02 25MM
815-2128	QUANTEC AXXESS ENG LX 25-6 /.06 17MM #1
815-2129	QUANTEC AXXESS ENG LX 25-8 /.08 17MM
815-2130	QUANTEC AXXESS ENG LX 25-8 /.08 21MM
815-2131	QUANTEC AXXESS ENG LX 25 /.10 17MM
815-2132	QUANTEC AXXESS ENG LX 25 /.10 21MM
815-2133	QUANTEC AXXESS ENG LX 25 /.12 17MM
815-2134	QUANTEC AXXESS ENG LX 25 /.12 21MM
815-2135	QUANTEC AXXESS ENG LX 25-8 /.08 25MM