

Annex VII EC Declaration of Conformity

Manufacturer Name and Address: Kerr Corporation also trading as Pentrol 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: Gutta Percha Points & Cartridges
Endo-003

Product Tradename(s): TF, TF Adaptive, Autofit, K3 Points and elements Gutta Percha Cartridge

Device Identification: see Attachment 1

Classification and Rule(s): IIa per Annex IX, Rule 8

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:

25 May 2021

Issue date



Name: Mark Dzendzel

Title: Director, Quality Assurance Systems



Gutta Percha Points & Cartridges – Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
12643	GUTTA PERCHA TAPERED-XF (X-FINE) BX 100
12644	GUTTA PERCHA TAPERED-F (FINE) BX 100
12645	GUTTA PERCHA TAPERED-M (MEDIUM) BX 100
12646	GUTTA PERCHA TAPERED-L (LARGE) BX 50
12647	GUTTA PERCHA TAPERED-ASST (XF-FF-MF-F-FM-M) BX100
12648	GUTTA PERCHA STD- #15 BX 100
12649	GUTTA PERCHA STD- #20 BX 100
12650	GUTTA PERCHA STD- #25 BX 100
12651	GUTTA PERCHA STD- #30 BX 100
12652	GUTTA PERCHA STD- #35 BX 100
12653	GUTTA PERCHA STD- #40 BX 100
12654	GUTTA PERCHA STD- #45 BX 100
12655	GUTTA PERCHA STD- #50 BX 100
12656	GUTTA PERCHA STD- #55 BX 100
12657	GUTTA PERCHA STD- #60 BX 100
12658	GUTTA PERCHA STD- #70 BX 100
12659	GUTTA PERCHA STD- #80 BX 100
13985	GUTTA PERCHA TAPERED-FF (FINE-FINE) BX 100
13986	GUTTA PERCHA TAPERED-MF (MEDIUM-FINE) BX 100
13987	GUTTA PERCHA TAPERED-FM (FINE-MEDIUM) BX 100
14374	GUTTA PERCHA TAPERED-ASST (XF-FF-MF-F-FM-M) 6 VIALS OF 20
14375	GUTTA PERCHA TAPERED-F (FINE) 6 VIALS OF 20
14376	GUTTA PERCHA TAPERED-XF (X-FINE) 6 VIALS OF 20
14377	GUTTA PERCHA TAPERED-FF (FINE-FINE) 6 VIALS OF 20
14378	GUTTA PERCHA TAPERED-MF (MEDIUM-FINE) 6 VIALS OF 20
14379	GUTTA PERCHA TAPERED-FM (FINE-MEDIUM) 6 VIALS OF 20
14380	GUTTA PERCHA TAPERED-M (MEDIUM) 6 VIALS OF 20
14381	GUTTA PERCHA TAPERED-L (LARGE) 6 VIALS OF 12
14382	GUTTA PERCHA STD- #15 6 VIALS OF 20
14383	GUTTA PERCHA STD- #20 6 VIALS OF 20
14384	GUTTA PERCHA STD- #25 6 VIALS OF 20
14385	GUTTA PERCHA STD- #30 6 VIALS OF 20
14386	GUTTA PERCHA STD- #35 6 VIALS OF 20
14387	GUTTA PERCHA STD- #40 6 VIALS OF 20
14388	GUTTA PERCHA STD- #45 6 VIALS OF 20
14389	GUTTA PERCHA STD- #50 6 VIALS OF 20
14390	GUTTA PERCHA STD- #55 6 VIALS OF 20
14391	GUTTA PERCHA STD- #60 6 VIALS OF 20
14392	GUTTA PERCHA STD- #70 6 VIALS OF 20
14393	GUTTA PERCHA STD- #80 6 VIALS OF 20
14451	GUTTA PERCHA STD- ASST #15-40 6 VIALS OF 20
14452	GUTTA PERCHA STD- ASST #45-80 6 VIALS OF 20
14453	GUTTA PERCHA STD- ASST #90-140 6 VIALS OF 20
815-1540	TF ADAPTIVE GUTTA PERCHA POINT, SIZE SM2 - 50PK
815-1541	TF ADAPTIVE GUTTA PERCHA POINT, SIZE SM3 - 50PK
815-1542	TF ADAPTIVE GUTTA PERCHA POINT, ASST. SM2 & SM3 - 50PK
815-1543	TF ADAPTIVE GUTTA PERCHA POINT SIZE ML1 - 50PK
815-1544	TF ADAPTIVE GUTTA PERCHA POINT SIZE ML2 - 50PK
815-1545	TF ADAPTIVE GUTTA PERCHA POINT SIZE ML3 - 50PK
815-1546	TF ADAPTIVE GUTTA PERCHA POINT ASST. ML1, ML2 & ML3 - 50PK
822-0010	TF GUTTA PERCHA POINTS, ASSORTED .04 THRU .12-S TAPER
822-0020	TF APICAL GUTTA PERCHA POINTS ASSTD. (50 PK)
822-0425	TF GUTTA PERCHA POINTS .04 TAPER
822-0440	TF APICAL GUTTA PERCHA POINTS .04/40 (50 PK)



Gutta Percha Points & Cartridges / Endo-003	
REF	Description
822-0450	TF APICAL GUTTA PERCHA POINTS .04/50 (50 PK)
822-0625	TF GUTTA PERCHA POINTS .06 TAPER
822-0630	TF APICAL GUTTA PERCHA POINTS .06/30 (50 PK)
822-0635	TF APICAL GUTTA PERCHA POINTS .06/35 (50 PK)
822-0825	TF GUTTA PERCHA POINTS .08 TAPER
822-1025	TF GUTTA PERCHA POINTS .10 TAPER
822-1225	TF GUTTA PERCHA POINTS .12-S TAPER
825-0047	K3 GUTTA PERCHA .04 SIZE 50PK
825-0048	K3 GUTTA PERCHA .06 SIZE 50PK
825-0400	K3 GUTTA PERCHA .04/.20 THRU .40 ASSORTED 50PK
825-0420	K3 GUTTA PERCHA .04/.20 SIZE 50PK
825-0425	K3 GUTTA PERCHA .04/.25 SIZE 50PK
825-0430	K3 GUTTA PERCHA .04/.30 SIZE 50PK
825-0435	K3 GUTTA PERCHA .04/.35 SIZE 50PK
825-0440	K3 GUTTA PERCHA .04/.40 SIZE 50PK
825-0445	K3 GUTTA PERCHA .04/.45 SIZE 50PK
825-0600	K3 GUTTA PERCHA .06/.20 THRU .40 ASSORTED 50PK
825-0620	K3 GUTTA PERCHA .06/.20 SIZE 50PK
825-0625	K3 GUTTA PERCHA .06/.25 SIZE 50PK
825-0630	K3 GUTTA PERCHA .06/.30 SIZE 50PK
825-0635	K3 GUTTA PERCHA .06/.35 SIZE 50PK
825-0640	K3 GUTTA PERCHA .06/.40 SIZE 50PK
825-0645	K3 GUTTA PERCHA .06/.45 SIZE 50PK
952-0010	500-013 Fine-Fine Gutta Percha Box of 100
952-0011	500-014 Medium-Fine Gutta Percha Box 100
952-0012	500-015 Fine Gutta Percha Box of 100
952-0013	500-016 Fine-Medium Gutta Percha Box 100
952-0014	500-017 Medium Gutta Percha Box of 100
952-0015	500-018 Med-Large Gutta Percha Box 100
952-0016	500-019 Gutta Percha Non-Std L 100/Box
972-0020	Autofit Backfill Gutta Percha - Size F
972-0021	Autofit Backfill Gutta Percha - Size FM
972-0022	Autofit Backfill Gutta Percha - Size M
972-0023	Autofit Backfill Gutta Percha - Size ML
972-0100	06-12 ASST., Autofit Greater Taper GP
972-0101	Size 04, Autofit Greater Taper Gutta
972-0102	Size 06 Autofit Greater Taper Gutta
972-0103	Size 08 Autofit Greater Taper Gutta
972-0104	Size 10 Autofit Greater Taper Gutta
972-0105	Size 12-L Autofit Greater Taper GP
972-0107	Size 12-S Autofit Greater Taper GP
972-1002	Elements Gutta Percha Cartridge Kit 23GA - PK 10
972-1003	Elements Gutta Percha Cartridge Kit 25GA - PK 10
972-1005	Elements Gutta Percha Cartridge Kit Heavy Body 23GA - PK 10