

Annex VII EU 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: OptiDisc/ R106

Product Tradename(s): OptiDisc™

Device Identification: See Attachment 1

Classification and Rule(s): Class IIa, Rule 5

Notified Body: BSI

Notified Body Number: 2797

Conformity Assessment Annex V

Procedure & Certificate issued: EC Certificate: CE 00847

Declaration Statement:

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

Regulatory Affairs Signature:

20 September 2021

Issue Date



Name: Mark Dzendzel

Title: Director, Quality Assurance Systems

OptiDisc/ R106 - Attachment 1 to Annex VII EU Declaration of Conformity	
REF	Description
187	OptiDisc Kit
4181	OPTIDISC coarse/medium 9.6mm, brown center
4182	OPTIDISC fine 9.6mm, orange center
4183	OPTIDISC extra-fine 9.6mm, yellow center
4184	OPTIDISC coarse/medium 12.6mm, brown center
4185	OPTIDISC fine 12.6mm, orange center
4186	OPTIDISC extra-fine 12.6mm, yellow center
4190	OPTIDISC ASSORTED KIT 15.9MM
4191	OPTIDISC coarse/medium 15.9mm, brown center
4192	OPTIDISC fine 15.9mm, orange center
4193	OPTIDISC extra-fine 15.9mm, yellow center
4197	OPTIDISC extra-coarse 9.6mm, bordeaux center
4198	OPTIDISC extra-coarse 12.6mm, bordeaux center
4199	OPTIDISC extra-coarse 15.9mm, bordeaux center
P43900	Optidisc Sample
195	OPTIDISC standard mandrel
196	OPTIDISC short mandrel
4188	Hawe OptiDisc Kit for polishing and finishing
4200	OptiDisc General Assorted Kit
5100	Hawe Polishing Assorted Kit