

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:

16 December 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
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