

Annex IV EU Declaration of Conformity

Manufacturer Name and

Address:

Kerr Corporation

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

Single Registration Number

(SRN)

Not Assigned

Technical File Name/Number: Demi Plus

Project #760 and Technical File #R096

Basic UDI-DI: 0841396110000089S

Product Tradename(s): Demi Plus

Device Identification: See Attachment 1

Classification and Rule(s): Class I – Rule 13

Common Standards: N/A

Notified Body: N/A
Notified Body Number: N/A

Conformity Assessment Annex IV

Procedure & Certificate

issued:

CE certificate: N/A

Declaration Statement:

This declaration of conformity is issued under the sole responsibility of Kerr Corporation. We hereby declare that the above-mentioned device(s) comply with EU MDR 2017/745.

Signed for and on behalf of Manufacturer: Kerr Corporation

Orange, California, 31 March USA 2021

Place

10/100

Date of Mark Dzendzel

Issue Director, Quality Assurance Systems

DC MP 30-47
Rev. 15

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Kerr[®]

Demi Plus - Project #760 Technical File #R096 Attachment 1 to Annex IV EU Declaration of Conformity	
REF	Device Description
910860-1	Demi Plus (120 V)
910860-2	Demi Plus (230 V) Europe/UK
921918-1	Demi Pus Battery Pack
921919-1	Demi Plus Battery Charger
921920-1	Demi Plus Handpiece Replacement (without Light
	Guide or Battery)
921862-1	Demi Plus Upgrade Kit
952269	Demi and Demi Plus Power Supply
20816	Protective Light Shield
20399	Disposable Hardness Disk

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