

**Annex IV EC Declaration of Conformity**

**Manufacturer Name and Address:** Kerr Corporation  
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

**Single Registration Number (SRN):** Not available

**Technical File Name/Number:** Rubber Dam/ R110

**Basic UDI-DI:** See Attachment 1

**Product Tradename(s):** OptiDam™, SoftClamp™

**Device Identification:** See Attachment 1

**Classification and Rule(s):** Class I, Rule 5

**Common Standards:** Not available

**Notified Body:** Not applicable  
**Notified Body Number:** Not applicable

**Conformity Assessment Procedure & Certificate issued:** Annex IV of MDR 2017/745  
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.*

**Regulatory Affairs Signature:**

Place and Issue date:  
Orange, CA USA  
04 October 2021



Name: Mark Dzendzel  
Title: Director Quality Assurance Systems

<b>Technical File # R110 Rubber Dam</b> <b>Attachment 1 to Annex IV EC Declaration of Conformity</b>		
<b>REF</b>	<b>Description</b>	<b>Basic UDI-DI</b>
5200	OptiDam™ Posterior Intro Kit	084139611000085AC
5201	OptiDam™ Posterior Refill	
5202	OptiDam™ Frame Refill	
5203	OptiDam™ Anterior Intro Kit	
5204	OptiDam™ Anterior Refill	
5205	OptiDam™ Posterior Refill	
5206	OptiDam™ Anterior Refill	
5250	SoftClamp™ General Kit	084139611000088AJ