



**DECLARATION OF CONFORMITY**  
Orthovisc/Orthovisc *mini*

**Name and Address of the Manufacturer:**

Anika Therapeutics, Inc.  
32 Wiggins Avenue  
Bedford, MA 01730

**We declare under our sole responsibility that:**

Orthovisc and Orthovisc *mini*  
PN 630-250, 630-252, 630-257

**Of Class**

III, per Annex IX, Special Rule 8 of the Medical Device Directive (93/42/EEC)

**Meets all the provisions of the directive 93/42/EEC which apply to it and conforms to applicable applied harmonized standards, national standards or other normative documents referenced in the Essential Requirements Checklist, Document No. DD-001-02.**

**Conformity Assessment procedure:** Annex 2, Section 4 of 93/42/EEC

**Anika further certifies that the Quality Management System meets requirements of ISO 13485: 2003 and EN ISO 13485:2012 evidenced the following certifications**

ISO Certificate Number US02/2814  
EN ISO Certificate Number US15/842144  
EC Full QA System Certificate Number US96/7957

**Notified Body:**

SGS United Kingdom, Ltd.  
Unit 202b, Worle Parkway,  
Weston Super Mare,  
BS22 6WA,  
United Kingdom  
CE 0120

**Authorized European Representative:**

Anika Therapeutics, S.r.l.  
Corso Stati Uniti, 4/U  
35127 Padova (PD), Italy

**Signed for and on behalf of:**

Anika Therapeutics, Inc.  
32 Wiggins Avenue  
Bedford, MA 01730

**Validity Period of this Declaration of Conformity:**

Design Examination Certificate Number: US96/8034

Expiring on 21 September 2021

**Place and Date of Issue:**

Bedford, Massachusetts

26 July 2017

**Signed**

  
Regulatory Affairs Manager

  
Date