Declaration of Conformity
MONOVISC

Name and Address of the Manufacturer:

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

We declare under our sole responsibility that:

Monovisc®
PN 690-008, 690-015

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-007-03.

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: US07/1125

Valid from: 30May2018
Valid to: 27September2022

Place and Date of Issue:

Bedford, Massachusetts

30 May 2018

Signed

Vice President RA/CA

22-MAR-2019
Date