



EC DECLARATION OF CONFORMITY

Name and Address of the Manufacturer:

Anika Therapeutics, Inc.
32 Wiggins Avenue
Bedford, MA 01730
United States of America

We declare under our sole responsibility that:

Orthovisc and Orthovisc *mini*

Part Number	Description
630250	Orthovisc EU, 2.0ml
630252	Orthovisc mini, EU, 1.0ml
630257	Orthovisc EU, 2.0ml, Expanded Languages

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.

Conformity Assessment procedure: Annex II (Full Quality Assurance), covered by the MDD certificates as well as by the Conformity Assessment Procedure listed here in the Declaration of Conformity.

Anika further certifies that the Quality Management System meets requirements of ISO 13485: 2016 and EN ISO 13485:2016 evidenced the following certifications:

MDSAP (ISO 13485:2016) Certificate Number 36681
EN ISO 13485:2016 Certificate Number 36680

Notified Body:

GMED
1 rue Gaston Boissier,
75015 Paris Cedex 15, France
CE 0459

Authorized European Representative:

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

Declaration valid until: December 31st, 2027



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Orthovisc/Orthovisc *mini*

This declaration is supported by:

- EC certificate of Design Examination (Annex II) N°36823 rev. 2 issued by GMED on May 10, 2021 and additional document N°37214 rev. 7 issued by GMED on April 10, 2025;
- EC certificate of Approval of Full Quality Assurance System (Annex II excluding section 4) N°36826, rev. 1, issued by GMED on October 5, 2020 and the additional document N°37217 rev.6 issued by GMED on September 5, 2023.

Signed for and on behalf of:

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

Place: Bedford, Massachusetts, USA

Signed by:

A handwritten signature in black ink that reads "Wei Zhao".

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Wei Zhao

Executive Director, Regulatory Affairs

Date: 06-May-2025 | 7:38 PM EDT

Anika
Document Change History

Document Title: Declaration of Conformity Orthovisc/Orthovisc <i>mini</i>			Document #: GMP-DoC-0010
Change Number	Revision	Description of Changes	Effective Date
GMP-Packet-0477-25	01	<p>First issue of the document as infocard type “GMP-DoC”. Previous document reference: GMP-Form-0296. Changes made:</p> <ol style="list-style-type: none"> 1) Implemented changes introduced with amendment to DoC (Rev.A and B). 2) Added “United States of America” or “USA” on the manufacturer’s address. 3) Added validity date of the declaration of conformity. 4) Update of revision of DC n°37217. 	06-May-2025 7:38 PM