CERTIFICATE OF REGISTRATION

N° 36681–7

GMED certifies that the quality management system developed by

ANIKA THERAPEUTICS, Inc.

32 Wiggins Avenue

Bedford MA 01730 UNITED STATES

Facility identifier (REPs-generated) : F004920

for the activities

Conception et fabrication d'acide hyaluronique stérile pour application chirurgicale, ophtalmique, orthopédique. Conception et développement, fabrication et distribution d'ancillaires pour le domaine de la chirurgie orthopédique.

Design and manufacture of sterile hyaluronic acid for surgical, orthopaedic, ophthalmic application. Design and development, manufacture and distribution of ancillary Instruments for the Area of orthopaedic Surgery.

performed on the location(s) of

ANIKA THERAPEUTICS, Inc. 32 Wiggins Avenue Bedford MA 01730 USA

has been audited and found to conform to the requirements of the international standard ISO 13485 : 2016 and following regulatory requirements

Australia	Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
Canada	Medical Devices Regulations - Part 1 - SOR 98/282
United States	21 CFR 820 21 CFR 803 21 CFR 806 21 CFR 807 - -Subparts A to D 21 CFR 821 (where applicable)

Début de validité / *Effective date* **March 29th, 2025 (included)**

Valable jusqu'au / *Expiry date :* **March 28th, 2028 (included)**

Etabli le / *Issued on :* **March 31st, 2025**

Signé par : Romuald GORJUP 684DC6B491EA4B2...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President

Romuald GORJUP

Certification Director

GMED is recognised under the Medical Devices Single Audit Program
This certificate is issued according to the rules of GMED Certification
The validity of this certificate can be verified on www.gmed.fr

Annule et remplace le certificat 36681-6

720 GMED 0901-8 rev 1 du 21/JAN/2025