CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

GLW, Inc.

Main Site: 930 Sylvan Avenue, Englewood Cliffs, New Jersey, 07632, United States (FIN F006739)

Additional site: GLW Europe GmbH
Max-Planck-Str. 12, 78573 Wurmlingen, Deutschland (FIN F006740)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

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

The management system is applicable to:

The design, manufacture, and distribution of sterile Orthopedic implants and instruments.

Main Site: Management, design, purchasing

Additional Site: Design, purchasing

Certificate Number:
0159000

Revision Level: 01

Initial Certification Date:
2023-10-27

Certification Effective Date:
2024-12-09

Certification Expiry Date:
2026-10-26

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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