C E R T I F I C A T E

no. 429/23

ePrivacyseal GmbH
Große Bleichen 21, 20354 Hamburg, Germany

hereby certifies* that

as determined in the certification decision of 11 January 2023

Arthrex Inc.
1370 Creekside Boulevard, Naples, Florida 34108-1945, USA
as a processor in the sense of art. 4(8) GDPR

operates its product or service
„Arthrex Virtual Implant Positioning (VIP)“
version 6.1
as defined in annex 1 and to the exclusion of the processing activities in annex 2 to this certificate.

final audit day: 10/01/2023
next planned monitoring by 09/01/2025
period of validity: 10/01/2023 – 09/01/2025

The certification decision takes place under the validity condition described in Annex 3
and in conformity with the criteria catalogue of ePrivacyseal GmbH, version 3.0 of May 2022.

*ePrivacyseal GmbH is not an accredited certification body within the meaning of art. 42(5) GDPR.

Annex 1 to certificate no. 429/23

Definition of processing activities

The VIP™ preoperative planning system web portal is a medical device designed to facilitate the transfer of information between surgeons and Arthrex technicians. With purposeful functionality, the portal allows surgeons to make adjustments to protocol-based plans created by Arthrex technicians. Once the initial plan is created, it is uploaded into a web session within the portal, in which surgeons can adjust an implant's position and orientation on the isolated scapula in both 2D and 3D. The web portal also acts as a communication channel between surgeons and technicians throughout the approval process. Once a plan is approved in the portal, further changes are prohibited. Approved 2D and 3D plans can be accessed as locked PDF files via the "Viewer" page.

The VIP web portal is intended for use as a software interface and for the transfer of imaging information from a medical scanner such as a CT scanner. It is also intended as software for displaying/editing implant placement and surgical treatment options that were generated in the OrthoVis desktop software by trained Arthrex technicians. The VIP web portal is intended for use with the Arthrex glenoid targeter and with the Arthrex OrthoVis Preoperative Plan. It is indicated for use with the following glenoid implant lines: Arthrex Univers™ II and Arthrex Univers Apex, keeled or pegged glenoid components, the VaultLock® glenoid component, as well as the Univers Revers and Modular Glenoid System (MGS) baseplate components.

Annex 2 to certificate no. 429/23

Excluded processing activities

This evaluation refers only to the above mentioned product and therefore only to the processes in which Arthrex Inc. and its customers are involved. Any devices connected e.g. CT Scanner are not within the scope of this evaluation.

Annex 3 to certificate no. 429/23

Validity condition

The seal is awarded on the validity condition that the lawfulness of the transfer of personal data to a non-EEA country is ensured either by a) an adequacy decision or b) equivalent technical and organisational measures by the applicant that have been approved by the Certification Body.