Geuder®
Precision made in Germany

Confirmation Letter

December 4, 2023

To whom it may concern,

Geuder AG ranks among the leading manufacturers of ophthalmologic surgical instruments and devices. With more than 3,000 different precision instruments that are exported to more than 90 countries, the renowned Heidelberg-based company covers the entire range of instruments required for almost all surgical procedures on the eye. A high degree of precision and reliability and the connection of technological innovations with traditional craftsmanship are among the key elements of the company's future-oriented philosophy. The ophthalmic surgical instruments developed and produced by Geuder AG, meet the highest quality standards.

The quality of all GEUDER products and services is controlled by our quality assurance system, which fulfills the requirements of the European quality management standards DIN EN ISO 9001:2015, DIN EN ISO 13485:2016, Medical Device Single Audit Program (MDSAP) and the Medical Devices Directive (MDD) 93/42/EEC of the Council of 14 June 1993, as well as the Medical Device Regulation (MDR) Regulation (EU) 2017/745. This quality management system is described in GEUDER's quality manual and standard operating procedures (SOP's) which are certified by independent notified bodies (BSI UK, BSI NL, GMED). This certification authorizes us to label our products with the CE-Mark. As a part of this quality management system, we do maintain regional distribution partners on exclusive contract basis. These partners are subsequently qualified and authorized in order to carry-out the according local duties and services as required by the above indicated norms and our internal quality management system, for example:

- To record and take care on complaints, according DIN EN ISO 13485 (Chapter 8.2.2);
- To follow-up carry out local recalls and reportable incidents, according to DIN EN ISO 13485 (Chapter 8.2.3), MDR (Chapter VII, Section 2);
- To instruct end-users, concerning intended and purpose use and associated risks, according to DIN EN ISO 13485 (Chapter 7.5.3);
- To maintain a post market surveillance, according to DIN EN ISO 13485 (Chapter 8.2.1), MDR (Chapter VII, Section 1 and 3 / Annex III);
- To provide after sales service and warranty, according to DIN EN ISO 13485 (Chapter 7.5.4)

Herewith we do confirm that, our exclusive partner under contract in Lithuania is:

UAB Tradintek
J. Jasinskio Str. 9
01111 Vilnius
Lithuania

GEUDER Service and Warranty Declaration for Surgical Instruments

The maxim of precision and perfection of GEUDER products also applies to our after sales service. Professionalism and care are essential factors for our international success. With more than 40 highly qualified and experienced microsurgery mechanics and electronics engineers, we offer comprehensive maintenance and repair services for instruments, device systems and accessories. Our qualified service offers our customers the possibility to reduce costs by using their existing instruments and to purchase expensive new instruments only when really necessary.

We warrant that every GEUDER product that leaves the factory, is free from any defects in material and workmanship.

This warranty will be valid for the period of 5 years, starting on the day of the original delivery, defined by the date of the invoice.

The prerequisite to claim warranty is a professional use, reprocessing, care and handling of the products according to our official reprocessing instructions and manuals. Please refer to the recommendations of the IFU and the task force "AKI Task Force Reprocessing - Proper Maintenance of Instruments".

Excluded from this warranty, according to our terms and conditions (chapter 8) is any kind of damage which is not related to the manufacturing itself, such as:

- Damage due to usage which is not according to the product's intended use / "Misuse".
- Damage due to improper handling, cleaning and care during usage, disposal, reprocessing and storage, such as:
    - Unsuitable type or dosage of chemicals used.
    - Unsuitable washing, disinfection or sterilization methods.
    - Unsuitable care additives.
    - Unsuitable storage in the tray.
    - Insufficient water or steam quality.
    - Damage due to regular wear and tear.
    - Damage due to careless handling, including overstressing or dropping.
    - Disassembling, repair or modification by a customer or third party.
    - Malfunctions due to usage with defective accessories or components which are not certified by GEUDER.
    - Transport damage that may occur due to inadequate packaging or non-use of protective accessories
    - Unsuitable and/or unauthorized previous repair, service or maintenance by unauthorized 3rd parties

GEUDER AG
Hertzstraße 4
(Phone) (+49) 06221/3060
D-69126 Heidelberg

Olcayto Gülec
Director Global Sales