Information Sheet for Customers and Users

in accordance with Article 14 of Regulation (EU) 2017/745 (MDR)

Berger Surgical Medical Products GmbH
take-off-Gewerbepark 4
D - 78579 Neuhausen ob Eck
Phone: +49 7467 949770
Web: www.berger-surgical.de

1. Purpose of this Information Sheet

This document provides relevant information for customers and users regarding the distribution of medical devices in accordance with Article 14 of Regulation (EU) 2017/745 (MDR).

2. Ensuring Product Compliance

As a distributor, we ensure that the products supplied:

- bear a valid CE marking
- are accompanied by an EU declaration of conformity
- comply with applicable regulatory requirements
- are provided with required labeling and instructions for use

3. Instructions for Use

- Products must be used strictly in accordance with the instructions for use
- All safety-related instructions must be observed
- Please contact us at any time if you have questions regarding product use

4. Storage and Transport

Products must be stored and transported in accordance with the manufacturer’s specifications to ensure quality and safety.

5. Product Training

We support you in the safe use of our products:

Product training is provided upon request.

Please contact us if required.

6. Incident Reporting

If you:

- identify defects or deviations

- or observe a serious incident

please inform us immediately.

7. Traceability

Relevant delivery and product information is documented in accordance with legal requirements to ensure traceability.

8. Contact

For questions, training requests, or incident reporting, please contact:

Berger Surgical Medical Products GmbH
Phone: +49 7467 949770
Web: www.berger-surgical.de