## Worte der Geschäftsleitung:

As manufacturers of medical products such as bed positioning systems for sick and injured persons, therapeutic aids, medical mattresses, and decubitus prophylaxis and wound care systems (Class IIb), we are conscious of the responsibility involved in manufacturing products used by the ill and the incapacitated. The use of such aids, both in the medical field and as home remedies, calls for systems that are simple and safe, and we are dedicated to making these aids available to our customers at cost-effective prices for the ultimate benefit of their patients. The well-being of patients is always our highest priority.

In order to prove our reliability as a medical product manufacturer, both internally as well as publicly, we support European guidelines stipulating that all medical products must undergo a conformity assessment process. The successful completion of this process is a CE mark of conformity. Medical products, especially sterile products that exceed the risk limits for Low-Risk Products (Class I) require not only internal documentation but also certification by a third party ("a notified body").

## Certification pursuant to ISO I 3485:2003 not only complies with statutory regulations but also provides us with the following benefits:

## **Internally**

- 1. Provides early detection of defects and potential for improvement
- 2. Helps to correct weak points
- 3. Reduces failure costs
- 4. Increases productivity
- 5. Motivates employees

## **Publicly**

- 1. Creates trust during the order-initiation process
- 2. Medical Device Operator Ordinance [Medizinproduktebetreiberverordnung] supports the decision to purchase
- 3. Improves competitiveness on domestic and international markets
- 4. Offers protection against liability claims due to higher traceability
- 5. Helps us to fulfil domestic statutory stipulations and guidelines and facilitates compliance with international guidelines

By introducing this quality management system, we are better able to respond to changes in field standards in an adequate and timely manner. The quality management system offers us transparency. Transparent processes and responsibilities facilitate the management of our company.



Melanie Unterwurzacher Geschäftsführerin



Denise Unterwurzacher Geschäftsführerin