

To Whom It May Concern:

## **TECHNICAL STATEMENT**

### **Shelf life of STERIKING® Self Sealable Pouches**

The shelf life of STERIKING® packaging materials is determined based on supplier product data, our research and on collecting historical evidence from final users.

This statement is not applying to final packs (packed and sterilized) while those are within responsibility of a device producer.

It is recommended that the STERIKING® products are kept in their original, closed transport cartons and stored in dry, clean conditions protected from direct sunlight and excessive heat or moisture.

**Both the manufacturing date and a normative, referenced expiry date are stated on the carton label.** The expiry date is to be considered as a "Best before" guideline. There is no collapsing of product performance after the stated time period. Critical parts of a self seal pouch construction are the process indicators and the closing tape strip. When stored in their original transport carton, products do not become challenged by environmental conditions, but the drying out process of a adhesive system cannot be stopped by a packing system completely.

Depending on specific requirements of a final user, self seal pouches - older than the "Best before" date guides - may still be used if the storage conditions were according to the recommendations. For greater safety, it is advisable to test the product prior to its use.

Our tests have concluded a safe use within two years. Longer periods are recorded from practical users.

## **WIPAK OY**

### **Wipak Medical**