

## Declaration of Conformity

Wipak Oy  
P.O. Box 45  
15561 Nastola  
Finland

herewith declares that the following products:

- STERIKING® Crepe Papers (code - SPC)
- STERIKING® Reinforced Crepes (code - SCB)
- STERIKING® Nonwovens (code - NW)
- STERIKING® Prowraps (code - SMX)

to which this declaration relates are registered by Finnish competent authority, National Supervisory Authority for Welfare and Health, in reference to the European Medical Device Directive 93/42/EEC and its amendment 2007/47/EC (later called MDD), as well as are in conformance with the standards and norms listed below:

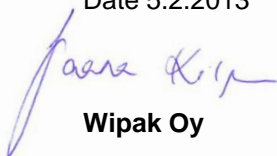
- ISO 11607-1:2006  
*Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.*
- EN 868-2:2009  
*Packaging for terminally sterilized medical devices – Part 2: Sterilizations wrap – Requirements and test methods.*

The STERIKING® sterilization wrapping materials, which are supplied by Wipak Oy to converters and packers in non sterile condition are class 1/ accessories under the MDD.

The STERIKING® sterilization packaging materials conform to the essential requirements set out in the MDD. The materials and packagings are developed to maintain sterility of a packed and processed device and they are for single use only.

The conformance to the MDD is shown by affixing the CE mark on each carton label.

Date 5.2.2013



**Wipak Oy**

