

Declaration of Conformity

Wipak Oy
Wipaktie 2
FI-15560 Nastola
Finland

herewith declares that the following products:

- STERIKING® See-Through Heat-Sealable Pouches (code – S)
- STERIKING® See-Through Gusseted Pouches (code – B)
- STERIKING® See-Through Heat-Sealable Rolls (code – R)
- STERIKING® See-Through Gusseted Rolls (code – RB)
- STERIKING® See-Through Self-Sealable Pouches (code – SS, SS-T)
- STERIKING® LT-Blueline Heat-Sealable Pouches (code – LTS)
- STERIKING® LT-Blueline Heat-Sealable Rolls (code – LTR)
- STERIKING® LT-Blueline Self-Sealable Pouches (code – LTSS)
- STERIKING® TEX-Line Peel Pouches (code – SNW)

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/Amd 1:2014
*Packaging for terminally sterilized medical devices –
Part 1: Requirements for materials, sterile barrier systems and packaging systems.*
- ISO 11607-2:2006/Amd 1:2014
*Packaging for terminally sterilized medical devices –
Part 2: Validation requirements for forming, sealing and assembly processes*
- EN 868-5:2009
*Packaging for terminally sterilized medical devices –
Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods*
- ISO 13485:2003
Medical devices – Quality management systems – Requirements for regulatory purposes

The STERIKING® sterilization packaging 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 4.11.2016



Wipak Oy

Wipak Oy
Wipak Health
Finland

Mail Address:
P.O.Box 45, FI-15561 Nastola
Visiting address:
Wipaktie 2, FI-15560 Nastola

Tel: +358-(0) 20-510 311
Fax +358-(0) 20-510 3300
E-mail: steriking@wipak.com
Website: www.steriking.info