Declaration of Conformity

Wipak Oy
Wipaktie 2
FI-15560 Nastola
Finland

herewith declares that the following products:

- STERIKING® Crepe Papers (code - SPC)
- STERIKING® Super Crepe Blue (code - SCB)
- STERIKING® Nonwovens (code - NW)
- STERIKING® ProWraps (code - SMX)
- STERIKING® CombiWraps (code - CW)

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 11607-1:2019
  Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems.

- EN 868-2:2017
  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 29.7.2019

WIPAK OY

Wipak Oy

Wipak Oy
Wipak Health
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