

EU Declaration of Conformity

according to Medical Device Regulation 2017/745, Annex IV

Manufacturer, SRN: FI-MF-000004496

Registered Trademark: Steriking®

Address: Wipaktie 2, 15560 Nastola, Finland

Product/device groups (detailed product list on next page):

- 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)
- STERIKING® Pouches for robotic instruments (code – SdV, SSdV)

Basic-UDI-DI: 6438263ST14010NK

to which this declaration relates conform to requirements set out in the Medical Devices Regulation (EU) 2017/745 (MDR), 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.*
- ISO 11607-2:2019 – *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*
- EN 868-5:2019 – *Packaging for terminally sterilized medical devices – Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods*
- ISO 13485:2016 – *Medical devices – Quality management systems – Requirements for regulatory purposes*
- ISO 14971:2019 – *Medical devices – Application of risk management to medical devices*

Above listed devices are designed to be used by trained healthcare professionals in healthcare facilities to allow sterilization, maintain sterility, and enable aseptic presentation of a packed and processed device, and they are for single use only.

The STERIKING® sterilization packaging materials, which are supplied by Wipak Oy in non sterile condition, are class I accessories by the MDR Annex VIII, Chapter III, Rule 1.

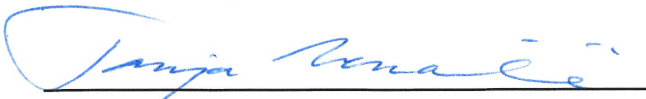
This declaration has been issued under the sole responsibility of the Wipak Oy.

Originally issued 25.5.2021

Updated: 25.5.2021

Reviewed:25.5.2021

On behalf of Wipak Oy in Nastola, Finland,



Tanja Venäläinen
Regulatory Affairs Manager

List of product references that this Declaration of Conformity concerns:

Tradename	Product references
STERIKING® See-Through Heat-Sealable Pouches	S1; S2; S3; S4; S5; S6; S7; S7A; S8; S9; S10; S10A; S11; S12; S13; S14; S15; S16; S17; S18; S19; S20; S21; S22; S23; S24; S25; S26; S27; S28; S29; S30; S31; S32; S33; S34; S35; S36; S37; S38; S2030; S2070; S1-3P; S2-3P; S3-3P; S4-3P; S5-3P; S6-3P; S7-3P; S7A-3P; S8-3P; S9-3P; S10-3P; S10A-3P; S11-3P; S12-3P; S13-3P; S14-3P; S15-3P; S16-3P; S17-3P; S18-3P; S19-3P; S20-3P; S21-3P; S22-3P; S23-3P; S24-3P; S25-3P; S26-3P; S27-3P; S28-3P; S29-3P; S30-3P; S31-3P; S32-3P; S33-3P; S34-3P; S35-3P; S36-3P; S37-3P; S38-3P; S2030-3P; S2070-3P
STERIKING® See-Through Gusseted Pouches	B30; B31; B32; B33; B34; B35; B36; B37; B38; B30-3P; B31-3P; B32-3P; B33-3P; B34-3P; B35-3P; B36-3P; B37-3P; B38-3P
STERIKING® See-Through Heat-Sealable Rolls	R39; R40; R41; R125; R42; R43; R44; R45; R46; R47; R39-3P; R40-3P; R41-3P; R125-3P; R42-3P; R43-3P; R44-3P; R45-3P; R46-3P; R47-3P; R39/100; R40/100; R41/100; R42/100; R43/100; R44/100; R45/100; R46/100; R47/100; R49/100; R39-3P/100; R40-3P/100; R41-3P/100; R42-3P/100; R43-3P/100; R44-3P/100; R45-3P/100; R46-3P/100; R47-3P/100; R49-3P/100; R39/31; R40/31; R41/31; R42/31; R43/31; R44/31; R45/31; R46/31; R47/31; R49/31; R39-3P/31; R40-3P/31; R41-3P/31; R42-3P/31; R43-3P/31; R44-3P/31; R45-3P/31; R46-3P/31; R47-3P/31; R49-3P/31
STERIKING® See-Through Gusseted Rolls	RB50; RB51; RB52; RB53; RB54; RB55; RB56; RB57; RB58; RB59; RB50-3P; RB51-3P; RB52-3P; RB53-3P; RB54-3P; RB55-3P; RB56-3P; RB57-3P; RB58-3P; RB59-3P
STERIKING® See-Through Self-Sealable Pouches	SS1; SS2; SS3; SS4; SS4A; SS5; SS5A; SS6; SS7; SS10; SS-T1; SS-T2; SS-T3A; SS-T4; SS-T4A; SS-T5A; SS-T6; SS-T7
STERIKING® LT-Blueline Heat-Sealable Pouches	LTS7520; LTS1025; LTS1057; LTS1530; LTS1644; LTS1660; LTS2038; LTS2538; LTS2550; LTS3040; LTS3057; LTS4050
STERIKING® LT-Blueline Heat-Sealable Rolls	LTR40; LTR41; LTR42; LTR43; LTR43A; LTR44; LTR45; LTR46; LTR47; LTR49
STERIKING® LT-Blueline Self-Sealable Pouches	LTSS1; LTSS2; LTSS3A; LTSS4; LTSS4A; LTSS5A; LTSS6; LTSS7
STERIKING® TEX-Line Peel Pouches	SNW2040; SNW2744; SNW3250; SNW4260; SNW5065; SNW5075; SNW5775
STERIKING® Pouch for Robotic Instruments	SdV10; SdV20; SSdV10; SSdV20