

EU DECLARATION OF CONFORMITY

We, Sterimed s.r.o., Evropská 866, Modřice 664 42, Czech Republic.

Considered as a medical device Manufacturer, registered under:

- system reference number CZ-MF-000006577 in EUDAMED database

Hereby certify, under our sole responsibility, that the following products:

STERISHEET STERILIZATION WRAPS

- is a Class I non-invasive medical device, according to definitions and rule 1 of classification on the Annex VIII of 2017/745 EU MDR.
- is intended to be used as sterilization wraps according to harmonized standard EN ISO 11607-1, delivered non-sterile and used for sterilization packaging of medical devices in hospitals and healthcare facilities
- the GMDN code 13735 (Sterilization packaging, single use)
- the Basic UDI-DI reference is 3662849SD00302113NN

The range of products is listed in Annex I of this document:

| Range |
|--|
| Sterisheet Sterilization Wraps – Single Sheets |
| Sterisheet Sterilization Wraps – Interleaved |
| Sterisheet Sterilization Wraps – DUO |
| Sterisheet Sterilization Wraps – Bonded |

- comply with the general safety and performance requirements of the EU Medical Device Regulation 2017/745 as demonstrated in technical file: Sterilization Wraps - Revision F.

The conformity assessment procedure was established according to:

- Article 52. §7 after drawing up the technical documentation set out in Annexes II and III of the 2017/745 EU MDR.

Expiration Date of this declaration: 2026-06-30

This declaration of conformity is valid in relation to the release document corresponding lot of manufactured products.

Modřice,

Tuesday, 16 November 2021



Michal CENTNER

Site Manager

STERIMED s.r.o.

se sídlem Modřice, Evropská 866, PSČ: 664 42, IČ: 274 35 474, zapsaná v obchodním rejstříku vedeném Krajským soudem v Brně, oddíl C., vložka 53147

with its registered seat at Modřice, Evropska 866, ZIP Code: 664 42, ID: 274 35 474, registered with the commercial register maintained by the District court in Brno, section C., entry 53147

Appendix 1: List and Product codes (full product code is based on the four (4) digits of product code and three (3) additional digits indicating the size of the sheet/set).

| Range | Product name | Code per Color | | |
|--|---------------------------|----------------|------|-------|
| | | White | Blue | Green |
| Sterisheet sterilization wraps – single sheets | STERISHEET 160 CREPE | 0063 | 0065 | 0067 |
| | STERISHEET 152 SOFT | 0703 | NA | 0739 |
| | STERISHEET 160 SOFT | 0071 | 0075 | 0079 |
| | STERISHEET 252 REINFORCED | NA | 0157 | NA |
| | STERISHEET 260 REINFORCED | NA | 0836 | NA |
| | STERISHEET 270 REINFORCED | NA | 0L09 | 0115 |
| | STERISHEET 357 NW | NA | 0B36 | 0C20 |
| | STERISHEET 360 NW | NA | 0681 | 0135 |
| | STERISHEET 366 NW | NA | NA | 0153 |
| | STERISHEET 378 NW | NA | 0129 | NA |
| | STERISHEET 340 SMS | NA | 0D93 | 0D06 |
| | STERISHEET 347 SMS | NA | 0D94 | 0D07 |
| | STERISHEET 355 SMS | NA | 0D95 | 0D08 |
| | STERISHEET 363 SMS | NA | 0D96 | 0D09 |
| STERISHEET 370 SMS | NA | 0D97 | 0D10 | |
| Sterisheet Sterilization Wraps – Bonded | STERISHEET BONDED 2 | 0F27 | NA | NA |
| | STERISHEET BONDED 3 | 0F66 | NA | NA |
| | STERISHEET BONDED 4 | 0F28 | NA | NA |
| | STERISHEET BONDED 5 | 0F29 | NA | NA |
| Sterisheet sterilization Wraps – DUO | STERISHEET DUO 1 | 0F30 | NA | NA |
| | STERISHEET DUO 2 | 0F31 | NA | NA |
| | STERISHEET DUO 3 | 0F32 | NA | NA |

| Range | Product name | White / Green | White / Blue | Green / Blue | Blue / Blue |
|-------------------------------|---|---------------|--------------|--------------|-------------|
| Interleaved | INTERLEAVED 160 CREPE W/160 CREPE G | 0235 | NA | NA | NA |
| | INTERLEAVED 160 CREPE W/160 CREPE B | NA | 0249 | NA | NA |
| | INTERLEAVED 152 SOFT W/160 CREPE G | 0913 | NA | NA | NA |
| | INTERLEAVED 160 SOFT W/160 SOFT G | 0237 | NA | NA | NA |
| | INTERLEAVED 160 SOFT W/160 SOFT B | NA | 0941 | NA | NA |
| | INTERLEAVED 160 SOFT G/160 SOFT B | NA | NA | 0228 | NA |
| | INTERLEAVED 160 SOFT G/260 REINFORCED B | NA | NA | 0895 | NA |
| | INTERLEAVED 160 SOFT W/260 REINFORCED B | NA | 0891 | NA | NA |
| | INTERLEAVED 160 SOFT W/360 NW B | NA | 0B54 | NA | NA |
| | INTERLEAVED 160 SOFT W/357 NW B | NA | 0F05 | NA | NA |
| | INTERLEAVED 160 SOFT G/357 NW B | NA | NA | 0C26 | NA |
| | INTERLEAVED 260 REINFORCED B/270 REINFORCED G | NA | NA | 0892 | NA |
| | INTERLEAVED 260 REINFORCED B/357 NW G | NA | NA | 0F08 | NA |
| | INTERLEAVED 260 REINFORCED B/360 NW B | NA | NA | NA | 0894 |
| | INTERLEAVED 260 REINFORCED B/366 NW G | NA | NA | 0897 | NA |
| | INTERLEAVED 260 REINFORCED B/378 NW B | NA | NA | NA | 0890 |
| | INTERLEAVED 357 NW G/357 NW B | NA | NA | 0C23 | NA |
| | INTERLEAVED 357 NW G/378 NW B | NA | NA | 0916 | NA |
| | INTERLEAVED 357 NW B/366 NW G | NA | NA | 0F07 | NA |
| | INTERLEAVED 357 NW G/378 NW B | NA | NA | 0F06 | NA |
| INTERLEAVED 360 NW B/366 NW G | NA | NA | 0C40 | NA | |
| INTERLEAVED 366 NW G/378 NW B | NA | NA | 0914 | NA | |
| INTERLEAVED 366 NW B/360 NW G | NA | NA | 0282 | NA | |
| Interleaved | INTERLEAVED 340 SMS B/340 SMS G | NA | NA | 0F33 | NA |
| | INTERLEAVED 355 SMS B/355 SMS G | NA | NA | 0F34 | NA |
| | INTERLEAVED 347 SMS B/355 SMS G | NA | NA | 0F35 | NA |
| | INTERLEAVED 370 SMS B/355 SMS G | NA | NA | 0F36 | NA |
| | INTERLEAVED 357 NW G/347 SMS B | NA | NA | 0F40 | NA |
| | INTERLEAVED 357 NW G/355 SMS B | NA | NA | 0F71 | NA |
| | INTERLEAVED 355 SMS B/ 360 NW G | NA | NA | 0F58 | NA |
| | INTERLEAVED 160 SOFT G/340 SMS B | NA | NA | 0F69 | NA |
| | INTERLEAVED 260 REINFORCED B/355 SMS G | NA | NA | 0F70 | NA |
| | INTERLEAVED 340 SMS G/260 REINFORCED B | NA | NA | 0FZ0 | NA |
| | INTERLEAVED 340 SMS G/355 SMS B | NA | NA | 0F68 | NA |
| | INTERLEAVED 357 NW G/363 SMS B | NA | NA | 0H12 | NA |

STERIMED s.r.o.

se sídlem Modřice, Evropská 866, PSČ: 664 42, IČ: 274 35 474, zapsaná v obchodním rejstříku vedeném Krajským soudem v Brně, oddíl C., vložka 53147

with its registered seat at Modřice, Evropska 866, ZIP Code: 664 42, ID: 274 35 474, registered with the commercial register maintained by the District court in Brno, section C., entry 53147