

EC-DECLARATION OF Conformity

We, Sterimed s.r.o, Evropska 866 – Modrice 664 42, Czech Republic.

Considered as a medical device Manufacturer, registered by N°27435474 in Czech Republic,

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 VII 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 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 European Medical device Regulation 2017/745 (MDR) 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 MDR 2017/745.

Expiration Date of this declaration: 2025-01-31,

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

Modrice,

Friday, 06 March 2020



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 Modrice, 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	Products' name	Code per Colour		
		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	NA	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	Products' 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	INTERLEAVED 366 NW G/378 NW B	NA	NA	0914	NA
	INTERLEAVED 366 NW B/360 NW G	NA	NA	0282	NA
	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	0F20	NA
	INTERLEAVED 340 SMS G/355 SMS B	NA	NA	0F68	NA
	INTERLEAVED 357 NW G/363 SMS B	NA	NA	0H12	NA

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