



# UE Conformity Declaration

SOGEVA Srl in quality of Manufacturer and sole responsible for medical devices sold into market with its own brand and name declares under its own responsibility that the device object of this declaration is conforming to general requirements of safety and performance requested by Encl. I of (UE) 2017/745 Norm.

Manufacturer	<b>SOGEVA Srl – Via Pietro Nenni snc – 23801 Calolziocorte (Lecco) Italia</b>
SRN Manufacturer number	//
Medical Device	<b>REELS AND POUCHES FOR STERILIZATION</b>
Basic UDI-DI	//
Class	<b>Class I Rule 1 Encl VIII Norm (UE) 2017/745</b>
Conformity Assesment Procedure	UE 2017/745 Rule: Encl II – Technical documentation Encl III –Post-marketing surveillance technical documentation

**Any modification made to the Medical Device if not authorized by SOGEVA Srl cancels the validity of this declaration.**

We declare that the device in question is sold in a non-sterile package.

We declare that the devices in question comply with the following technical standards:

- EN ISO 14971
- EN ISO 15223-1
- EN ISO 10993-1
- EN 62366

We declare that the undersigned will keep the documentation referred to in Annex I, II and III of Regulation (EU) 2017/745 available to the Competent Authority for a period of 10 years starting from the last production date of the devices in question. .

**Calolziocorte (LC) - ITALY, 5.5.2021**

**SOGEVA Srl**  
**Legale Rappresentante**  
Matteo SALA



SOGEVA s.r.l.  
L. Amministratore



**CODE LIST**

**FLAT REELS FOR STEAM AND GAS STERILIZATION - Length 200 mt**

CODE	SIZE	PACKING/WEIGHT
RSOGTUVCE50	mm 50x200 mt	08 Pcs/Cartron/Kg. 11,0
RSOGTUVCE75	mm 75x200 mt	05 Pcs/Cartron/Kg. 10,5
RSOGTUVCE100	mm 100x200 mt	04 Pcs/Cartron/Kg. 11,0
RSOGTUVCE150	mm 150x200 mt	02 Pcs/Cartron/Kg. 8,5
RSOGTUVCE200	mm 200x200 mt	02 Pcs/Cartron/Kg. 11,5
RSOGTUVCE250	mm 250x200 mt	01 Pc /Cartron/Kg. 7,0
RSOGTUVCE300	mm 300x200 mt	01 Pc /Cartron/Kg. 8,5
RSOGTUVCE400	mm 400x200 mt	01 Pc /Cartron/Kg. 10,5

**FLAT REELS FOR STEAM AND GAS STERILIZATION - Length 100 mt**

CODE	SIZE	PACKING/WEIGHT
R1SOGTUVCE50	mm 50x100 mt	08 Pcs/Cartron/Kg. 6,7
R1SOGTUVCE75	mm 75x100 mt	05 Pcs/Cartron/Kg. 6,0
R1SOGTUVCE100	mm 100x100 mt	04 Pcs/Cartron/Kg. 6,0
R1SOGTUVCE150	mm 150x100 mt	02 Pcs/Cartron/Kg. 4,0
R1SOGTUVCE200	mm 200x100 mt	02 Pcs/Cartron/Kg. 6,0
R1SOGTUVCE250	mm 250x100 mt	01 Pc /Cartron/Kg. 3,5
R1SOGTUVCE300	mm 300x100 mt	01 Pc /Cartron/Kg. 5,0
R1SOGTUVCE400	mm 400x100 mt	01 Pc /Cartron/Kg. 7,0
R1SOGTUVCE500	mm 500x100 mt	01 Pc /Cartron/Kg. 7,5
R1SOGTUVCE600	mm 600x100 mt	01 Pc /Cartron/Kg. 8,5

**GUSSETTED REELS FOR STEAM AND GAS STERILIZATION - Length 100 mt**

CODE	SIZE	PACKING/WEIGHT
RSSOGTUVCE75	mm 75xh25mmx100 mt	05 Pcs/Cartron/Kg. 7,50
RSSOGTUVCE100	mm 100xh50mmx100 mt	04 Pcs/Cartron/Kg. 8,50
RSSOGTUVCE150	mm 150xh50mmx100 mt	02 Pcs/Cartron/Kg. 5,50
RSSOGTUVCE200	mm 200xh55mmx100 mt	02 Pcs/Cartron/Kg. 7,00
RSSOGTUVCE250	mm 250xh65mmx100 mt	01 Pc /Cartron/Kg. 4,50
RSSOGTUVCE300	mm 300xh80mmx100 mt	01 Pc /Cartron/Kg. 5,50
RSSOGTUVCE400	mm 400xh60mmx100 mt	01 Pc /Cartron/Kg. 6,50

**GUSSETTED POUCHES FOR STEAM AND GAS STERILIZATION**

CODE	SIZE	PACKING/WEIGHT
BSSOGCE100x300	mm 100xh 50mmx300	1.000 Pcs/Cartron/Kg. 6,00
BSSOGCE150x400	mm 150xh 50mmx400	500 Pcs/Cartron/Kg. 5,50
BSSOGCE150x450	mm 150xh 50mmx450	500 Pcs/Cartron/Kg. 6,00
BSSOGCE200x400	mm 200xh 55mmx400	250 Pcs/Cartron/Kg. 3,50
BSSOGCE200x500	mm 200xh 55mmx500	250 Pcs/Cartron/Kg. 4,50
BSSOGCE250x500	mm 250xh 65mmx500	250 Pcs/Cartron/Kg. 5,30
BSSOGCE300x600	mm 300xh 80mmx600	500 Pcs/Cartron/Kg. 15,00
BSSOGCE500x600	mm 500xh110mmx600	500 Pcs/Cartron/Kg. 25,00

**AUTOSEALING POUCHES FOR STEAM AND GAS STERILIZATION**



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CODE	SIZE	PACKING/WEIGHT
ASOGCE60x110	mm60x110 (film length)	200 Pcs/Box
	mm60x140 (paper length)	24 Boxes/Carton/Kg. 5,5
ABLCE90X160	mm.90x130 (film lenght)	200 Pcs/Box
	mm.90x160 (paper lenght)	14 Boxes/Carton
ASOGCE90x230	mm90x230 (film length)	200 Pcs/Box
	mm90x260 (paper length)	08 Boxes/Carton/Kg. 6,0
ASOGCE90x330	mm90x330 (film length)	200 Pcs/Box
	mm90x360 (paper length)	4 Boxes/Carton/Kg. 9,0
ASOGCE140x250	mm140x250 (film length)	200 Pcs/Box
	mm140x295 (paper length)	06 Boxes/Carton/Kg. 7,2
	outer carton size cm.31,5x24x31	
ASOGCE140x330	mm140x330 (film length)	200 Pcs/Box
	mm140x360 (paper length)	04 Boxes/Carton/Kg. 8,5
ASOGCE190x330	mm190x330 (film length)	200 Pcs/Box
	mm190x360 (paper length)	04 Boxes/Carton/Kg. 7,9
	outer carton size cm.38x30x22	
ASOGCE230X365	mm230x365 (film length)	100 Pcs/Box/Kg. 1,2
	mm230x400 (paper length)	
ASOGCE300x370	mm300x370 (film length)	200 Pcs/Box
	mm300x410 (paper length)	02 Boxes/Carton/Kg. 7,0
	outer carton size cm.33,5x43,5x17,5	
ABLCE330x440	mm330x440 (film length)	200 Pcs/Box/Kg. 4,0
	mm330x470 (paper length)	
	outer carton size cm.50x35x8	
ABLCE70X230	mm70x230 (film lenght)	200 Pcs/Box
	mm 70x260 (paper lenght)	08 Boxes/Carton/Kg. 6,0

#### **FLAT POUCHES FOR STEAM AND GAS STERILIZATION**

BSOGCE50X250	mm 50x250	1.000 Pcs/Box/kg. 2,0
BSOGCE75X150	mm 75x150	2.000 Pcs/Box/kg. 1,8
BSOGCE75X200	mm 75x200	2.000 Pcs/Box/kg. 4,5
BSOGCE75X250	mm 75x250	1.000 Pcs/Box/kg. 2,8
BSOGCE75X300	mm 75x300	1.000 Pcs/Box/kg. 3,5
BSOGCE75X400	mm 75x400	1.000 Pcs/Box/kg. 4,5
BSOGCE100X150	mm 100x150	1.000 Pcs/Box/kg. 2,3
BSOGCE100X200	mm 100x200	1.000 Pcs/Box/kg. 2,8
BSOGCE100X250	mm 100x250	1.000 Pcs/Box/kg. 4,0
BSOGCE100X300	mm 100x300	1.000 Pcs/Box/kg. 4,5
BSOGCE100X350	mm 100x350	1.000 Pcs/Box/kg. 4,4
BSOGCE100X400	mm 100x400	1.000 Pcs/Box/kg. 6,0
BSOGCE100X450	mm 100x450	1.000 Pcs/Box/kg. 6,2
BSOGCE100X500	mm 100x500	1.000 Pcs/Box/kg. 6,3
BSOGCE100X550	mm 100x550	1.000 Pcs/Box/kg. 7,0
BSOGCE150X200	mm 150x200	1.000 Pcs/Box/kg. 4,5



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BSOGCE150X250	mm 150x250	1.000 Pcs/Cartron/kg. 6,0
BSOGCE150X300	mm 150x300	1.000 Pcs/Cartron/kg. 6,5
BSOGCE150x350	mm 150x350	1.000 Pcs/Cartron/kg. 7,5
BSOGCE150X400	mm 150x400	1.000 Pcs/Cartron/kg. 8,5
BSOGCE150X450	mm 150x450	1.000 Pcs/Cartron/kg. 9,0
BSOGCE200X300	mm 200x300	1.000 Pcs/Cartron/kg. 8,5 1.000 Pcs/Cartron/kg.
BSOGCE200X350	mm 200x350	12,0 1.000 Pcs/Cartron/kg.
BSOGCE200X400	mm 200x400	11,0 1.000 Pcs/Cartron/kg.
BSOGCE200X450	mm 200x450	12,0 1.000 Pcs/Cartron/kg.
BSOGCE200X500	mm 200x500	13,0 1.000 Pcs/Cartron/kg.
BSOGCE250X300	mm 250x300	10,5 1.000 Pcs/Cartron/kg.
BSOGCE250X350	mm 250x350	12,0 1.000 Pcs/Cartron/kg.
BSOGCE250X400	mm 250x400	13,0 1.000 Pcs/Cartron/kg.
BSOGCE250X450	mm 250x450	15,0 1.000 Pcs/Cartron/kg.
BSOGCE250X500	mm 250x500	16,0
BSOGCE300X400	mm 300x400	500 Pcs/Cartron/kg. 8,5
BSOGCE300X450	mm 300x450	1.000 Pcs/Cartron/kg. 9,0 1.000 Pcs/Cartron/kg.
BSOGCE300X500	mm 300x500	10,5 1.000 Pcs/Cartron/kg.
BSOGCE300X550	mm 300x550	11,0 1.000 Pcs/Cartron/kg.
BSOGCE300X600	mm 300x600	12,0 500 Pcs/Cartron/kg.
BSOGCE400X500	mm 400x500	13,0 500 Pcs/Cartron/kg.
BSOGCE400X550	mm 400x550	14,0 500 Pcs/Cartron/kg.
BSOGCE500X600	mm 500x600	20,0 500 Pcs/Cartron/kg.
BSOGCE600X600	mm 600x600	24,0