



SOGEVA Srl
Via Pietro Nenni snc
23801 Calolziocorte (Lecco) - ITALY
Tel. +39 0341 641687
www.sogevasrl.com

DICHIARAZIONE DI CONFORMITÀ UE

EU Declaration of Conformity

SOGEVA Srl in qualità di Fabbricante e quale unico responsabile per i dispositivi medici immessi in commercio a proprio nome dichiara, sotto la propria responsabilità, che il dispositivo al quale questa dichiarazione si riferisce è conforme ai requisiti generali di sicurezza e prestazione richiesti dall'allegato I del Regolamento (UE) 2017/745.

SOGEVA Srl as Manufacturer and sole responsible for the issue of this Declaration of Conformity, declares under its own responsibility, that the device which this declaration is addressed to is conform to the General Safety and Performance Requirements required by annex I of EU Medical Device Regulation 2017/745.

Fabbricante/Manufacturer	SOGEVA Srl – Via Pietro Nenni snc – 23801 Calolziocorte (Lecco) Italia
Numero registrazione Fabbricante <i>SRN Manufacturer number</i>	IT-MF-000026322
Tipologia del Dispositivo/Medical Device name	ROTOLE E BUSTE PER LA STERILIZZAZIONE Pouches and Reels for sterilization
UDI-DI di base <i>Basic UDI-DI</i>	803384470POUCHREELSR
Classificazione/Classification	Classe I, class I Regola 1 Allegato VIII Regolamento EU 2017/745 <i>Rule 1 Annex VIII EU Regulation 2017/745</i>
Marcatura del dispositivo <i>Conformity Assessment Procedure</i>	Regolamento UE 2017/745: Allegato II – Documentazione tecnica – technical documentations Allegato III – Documentazione tecnica sulla sorveglianza post-marketing – post market surveillance technical documentation

Qualunque modifica apportata al Dispositivo Medico se non autorizzata da SOGEVA Srl annulla la validità della presente dichiarazione.

Any modification applied to the device, if not expressly authorized by SOGEVA Srl, cancel the validity of this declaration

Si dichiara che il dispositivo in oggetto viene commercializzato in confezione non sterile.

It's here declared that the device to which this declaration is addressed to, is commercialized not sterile.

Si dichiara che i dispositivi in oggetto ottemperano alle seguenti norme tecniche:

it's here declared that the device to which this declaration is addressed to, is conforming to the following technical norms:

- EN ISO 14971
- EN ISO 15223-1
- EN ISO 11607-1
- UNI EN 868-5
- UNI EN ISO 11140-1:2015

Si dichiara che la scrivente terrà a disposizione dell'Autorità Competente la documentazione di cui all'Allegato I, II e III della Regolamento (UE) 2017/745 per un periodo di 10 anni a partire dall'ultima data di produzione dei dispositivi in oggetto.

It's here declared that subscribing company will keep all the documents mentioned in Annex II of EU Regulation 2017/745 available for Competent Authority for a period of 10 years from the last production of the device to which this declaration is addressed to.

Calolziocorte (LC) - ITALY, 25.06.2024

SOGEVA Srl
Legale Rappresentante
Matteo SALA



SOGEVA s.r.l.
L. Amministratore

CE



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ROTOLE PIATTI PER VAPORE EO GAS - FLAT REELS FOR STEAM AND GAS STERILIZATION - 200 mt		
CODE	SIZES	PACKING
RSOGTUVCE50	mm 50x200 mt	12 Pcs/Cartron
RSOGTUVCE75	mm 75x200 mt	08 Pcs/Cartron
RSOGTUVCE100	mm 100x200 mt	06 Pcs/Cartron
RSOGTUVCE150	mm 150x200 mt	04 Pcs/Cartron
RSOGTUVCE200	mm 200x200 mt	04 Pcs/Cartron
RSOGTUVCE250	mm 250x200 mt	02 Pcs /Cartron
RSOGTUVCE300	mm 300x200 mt	02 Pcs /Cartron
RSOGTUVCE400	mm 400x200 mt	02 Pcs /Cartron

ROTOLE PIATTI PER VAPORE EO GAS - FLAT REELS FOR STEAM AND GAS STERILIZATION - 100 mt		
CODE	SIZES	PACKING
R1SOGTUVCE50	mm 50x100 mt	12 Pcs/Cartron
R1SOGTUVCE75	mm 75x100 mt	08 Pcs/Cartron
R1SOGTUVCE100	mm 100x100 mt	06 Pcs/Cartron
R1SOGTUVCE150	mm 150x100 mt	04 Pcs/Cartron
R1SOGTUVCE200	mm 200x100 mt	04 Pcs/Cartron
R1SOGTUVCE250	mm 250x100 mt	02 Pcs/Cartron
R1SOGTUVCE300	mm 300x100 mt	02 Pcs/Cartron
R1SOGTUVCE400	mm 400x100 mt	02 Pcs/Cartron
R1SOGTUVCE500	mm 500x100 mt	02 Pcs/Cartron
R1SOGTUVCE600	mm 600x100 mt	02 Pcs/Cartron

ROTOLE A SOFFIETTO PER VAPORE EO GAS - GUSSETED REELS FOR STEAM AND GAS STERILIZATION - 100 mt		
CODE	SIZES	PACKING
RSSOGTUVCE75	mm 75xh25mmx100 mt	08 Pcs/Cartron
RSSOGTUVCE100	mm 100xh50mmx100 mt	06 Pcs/Cartron
RSSOGTUVCE150	mm 150xh50mmx100 mt	04 Pcs/Cartron
RSSOGTUVCE200	mm 200xh55mmx100 mt	04 Pcs/Cartron
RSSOGTUVCE250	mm 250xh65mmx100 mt	02 Pcs/Cartron
RSSOGTUVCE300	mm 300xh80mmx100 mt	02 Pcs/Cartron
RSSOGTUVCE400	mm 400xh80mmx100 mt	02 Pcs/Cartron

BUSTE PIATTE PER VAPORE EO GAS - FLAT POUCHES FOR STEAM AND/EO STERILIZATION		
CODE	SIZES	PACKING
BSOGCE50X250	mm 50x250	1.000 Pcs/Cartron
BSOGCE75X200	mm 75x200	1.000 Pcs/Cartron
BSOGCE75X250	mm 75x250	1.000 Pcs/Cartron
BSOGCE75X300	mm 75x300	1.000 Pcs/Cartron
BSOGCE100X250	mm 100x250	1.000 Pcs/Cartron
BSOGCE100X300	mm 100x300	1.000 Pcs/Cartron
BSOGCE150X250	mm 150x250	1.000 Pcs/Cartron
BSOGCE150X300	mm 150x300	1.000 Pcs/Cartron
BSOGCE150X400	mm 150x400	1.000 Pcs/Cartron
BSOGCE200X300	mm 200x300	1.000 Pcs/Cartron
BSOGCE200X400	mm 200x400	1.000 Pcs/Cartron
BSOGCE250X400	mm 250x400	1.000 Pcs/Cartron
BSOGCE250X450	mm 250x450	1.000 Pcs/Cartron
BSOGCE250X500	mm 250x500	1.000 Pcs/Cartron
BSOGCE300X500	mm 300x500	1.000 Pcs/Cartron
BSOGCE300X600	mm 300x600	1.000 Pcs/Cartron



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BSOGCE400X500	mm 400x500	1.000 Pcs/Carton
BSOGCE500X600	mm 500x600	1.000 Pcs/Carton

BUSTE AUTOSIGILLANTI PER VAPORE EO GAS - AUTOSEALING POUCHES FOR STEAM AND GAS STERILIZATION

CODE	SIZES	PACKING
ASOGCE60x110	mm60x110 (film length)	200 Pcs/Box
	mm60x140 (paper length)	50 Boxes/Carton
ASOGCE90x230	mm90x230 (film length)	200 Pcs/Box
	mm90x260 (paper length)	15 Boxes/Carton
ASOGCE140x250	mm140x250 (film length)	200 Pcs/Box
	mm140x295 (paper length)	10 Boxes/Carton
ASOGCE190x330	mm190x330 (film length)	200 Pcs/Box
	mm190x360 (paper length)	05 Boxes/Carton
ASOGCE230X365	mm230x365 (film length)	100 Pcs/Box
	mm230x400 (paper length)	05 Boxes/Carton
ASOGCE300x370	mm300x370 (film length)	200 Pcs/Box
	mm300x410 (paper length)	04 Boxes/Carton
ASOGCE330x440	mm330x440 (film length)	200 Pcs/Box
	mm330x470 (paper length)	04 Boxes/Box
ASOGCE70X230	mm70x230 (film lenght)	200 Pcs/Box
	mm 70x260 (paper lenght)	20 Boxes/Box

BUSTE A SOFFIETTO PER VAPORE EO GAS - GUSSETTED POUCHES FOR STEAM AND GAS STERILIZATION

CODE	SIZES	PACKING
BSSOGCE100x300	mm 100xh 50mmx300	1.000 Pcs/Box
BSSOGCE150x400	mm 150xh 50mmx400	1.000 Pcs/Box
BSSOGCE200x400	mm 200xh 55mmx400	500 Pcs/Box
BSSOGCE200x500	mm 200xh 55mmx500	500 Pcs/Box
BSSOGCE250x500	mm 250xh 65mmx500	500 Pcs/Box
BSSOGCE300x600	mm 300xh 80mmx600	500 Pcs/Box
BSSOGCE500x600	mm 500xh110mmx600	500 Pcs/Box