

EU DECLARATION OF CONFORMITY

Manufacturer: BOLSAPLAST, S.L.
C. Bernat Metge, 110-112
08205 Sabadell
España

SNR: ES-MF-000000951

Basic UDI (GMN): 8437016867BOLSAPLASTT4

Codes / Description: See attached list

UDI numbers: See attached list

GMDN: 13735

Risk Class: Class I

Classification Rule: Rule 1, non-invasive product

Intended purpose: Packaging for sterilization processes qualified according to Regulation 2017/745 as a medical device intended for the sterilization of products that are contemplated in article 1 of the afore mentioned regulation.

We hereby declare that above mentioned products are in conformity with **Regulation (EU) 2017/745 of the European Parliament and Council**. This EU declaration of conformity is issued under the sole responsibility of Bolsaplast, S.L.

Standard and CS used and conform to:

ISO 9001:2015

ISO 13485:2016

Products above mentioned are produced in conformity with EN 868-2/3/4:2017, EN 868-5:2019 and ISO 11607-1:2019 (Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems and products made with Tyvek® are also produced in conformity with EN 868-9:2009 (Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefins. Requirements and test methods).

All our products are adequate for hospital using, in sterilization processes of medical-surgical products and similar materials.

**Place and date
of issue:**

Sabadell, 3rd February 2025

Signature:



Name: Ignasi Pares
Function: Quality Manager

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ANNEX

List of products

Codes	Description		Dimensions		UDI - DI				
MBO1025	BOLSAPLAST	PAPER/FILM FLAT BAGS	75	150	1	84	37010679	73	2
MBO1000	BOLSAPLAST	PAPER/FILM FLAT BAGS	75	210	1	84	37010679	00	8
MBO1001	BOLSAPLAST	PAPER/FILM FLAT BAGS	75	280	1	84	37010679	01	5
MBO1027	BOLSAPLAST	PAPER/FILM FLAT BAGS	75	570	1	84	37016867	15	7
MBO1002	BOLSAPLAST	PAPER/FILM FLAT BAGS	75	580	1	84	37010679	02	2
MBO1003	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	200	1	84	37010679	03	9
MBO1004	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	240	1	84	37010679	04	6
MBO1029	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	250	1	84	37016867	31	7
MBO1005	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	280	1	84	37010679	05	3
MBO1026	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	300	1	84	37010679	83	1
MBO1006	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	420	1	84	37010679	06	0
MBO1067	BOLSAPLAST	PAPER/FILM FLAT BAGS	120	400	1	84	37016867	30	0
MBO1007	BOLSAPLAST	PAPER/FILM FLAT BAGS	150	210	1	84	37010679	07	7
MBO1008	BOLSAPLAST	PAPER/FILM FLAT BAGS	150	280	1	84	37010679	08	4
MBO1009	BOLSAPLAST	PAPER/FILM FLAT BAGS	150	320	1	84	37010679	09	1
MBO1010	BOLSAPLAST	PAPER/FILM FLAT BAGS	150	360	1	84	37010679	10	7
MBO1011	BOLSAPLAST	PAPER/FILM FLAT BAGS	200	320	1	84	37010679	11	4
MBO1012	BOLSAPLAST	PAPER/FILM FLAT BAGS	200	360	1	84	37010679	12	1
MBO1013	BOLSAPLAST	PAPER/FILM FLAT BAGS	200	420	1	84	37010679	13	8
MBO1068	BOLSAPLAST	PAPER/FILM FLAT BAGS	210	350	1	84	37016867	32	4
MBO1014	BOLSAPLAST	PAPER/FILM FLAT BAGS	250	360	1	84	37010679	14	5
MBO1015	BOLSAPLAST	PAPER/FILM FLAT BAGS	250	420	1	84	37010679	15	2
MBO1016	BOLSAPLAST	PAPER/FILM FLAT BAGS	250	500	1	84	37010679	16	9
MBO1044	BOLSAPLAST	PAPER/FILM FLAT BAGS	300	360	1	84	37016867	16	4
MBO1017	BOLSAPLAST	PAPER/FILM FLAT BAGS	300	420	1	84	37010679	17	6
MBO1018	BOLSAPLAST	PAPER/FILM FLAT BAGS	300	500	1	84	37010679	18	3
MBO1019	BOLSAPLAST	PAPER/FILM FLAT BAGS	400	580	1	84	37010679	19	0
MBO1020	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	550	1	84	37010679	20	6
MBO1021	BOLSAPLAST	PAPER/FILM FLAT BAGS	150	400	1	84	37010679	21	3
MBO1022	BOLSAPLAST	PAPER/FILM FLAT BAGS	100	580	1	84	37010679	22	0
MBO1023	BOLSAPLAST	PAPER/FILM FLAT BAGS	200	500	1	84	37010679	23	7
MBO1024	BOLSAPLAST	PAPER/FILM FLAT BAGS	300	580	1	84	37010679	24	4
MBO1063	BOLSAPLAST	PAPER/FILM FLAT BAGS	320	500	1	84	37016867	22	5
MBO1064	BOLSAPLAST	PAPER/FILM FLAT BAGS	320	600	1	84	37016867	23	2
MBO1065	BOLSAPLAST	PAPER/FILM FLAT BAGS	420	500	1	84	37016867	24	9
MBO1066	BOLSAPLAST	PAPER/FILM FLAT BAGS	420	600	1	84	37016867	25	6
MBO1051	BOLSAPLAST	PAPER/FILM FLAT BAGS	75	300	1	84	37016867	26	3
MBF1202	BOLSAPLAST	PAPER/FILM GUSSET BAGS	200x55	400	1	84	37010679	30	5
MRP1040	BOLSAPLAST	PAPER/FILM FLAT REELS	50	200	1	84	37010679	40	4
MRP1041	BOLSAPLAST	PAPER/FILM FLAT REELS	75	200	1	84	37010679	41	1

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MRP1042	BOLSAPLAST	PAPER/FILM FLAT REELS	100	200	1	84	37010679	42	8
MRP1043	BOLSAPLAST	PAPER/FILM FLAT REELS	125	200	1	84	37010679	43	5
MRP1044	BOLSAPLAST	PAPER/FILM FLAT REELS	150	200	1	84	37010679	44	2
MRP1045	BOLSAPLAST	PAPER/FILM FLAT REELS	200	200	1	84	37010679	45	9
MRP1046	BOLSAPLAST	PAPER/FILM FLAT REELS	250	200	1	84	37010679	46	6
MRP1047	BOLSAPLAST	PAPER/FILM FLAT REELS	300	200	1	84	37010679	47	3
MRP1050	BOLSAPLAST	PAPER/FILM FLAT REELS	350	200	1	87	37010679	36	7
MRP1048	BOLSAPLAST	PAPER/FILM FLAT REELS	400	200	1	84	37010679	48	0
MRP1051	BOLSAPLAST	PAPER/FILM FLAT REELS	450	200	1	84	37016867	21	8
MRP10491	BOLSAPLAST	PAPER/FILM FLAT REELS	500	100	1	84	37010679	67	1
MBT1160	BOLSAPLAST	TYVEK/FILM BAGS	75	210	1	84	37010679	49	7
MBT1161	BOLSAPLAST	TYVEK/FILM BAGS	100	280	1	84	37010679	51	0
MBT1162	BOLSAPLAST	TYVEK/FILM BAGS	150	320	1	84	37010679	52	7
MBT1163	BOLSAPLAST	TYVEK/FILM BAGS	200	420	1	84	37010679	53	4
MBT1164	BOLSAPLAST	TYVEK/FILM BAGS	250	500	1	84	37010679	54	1
MBT1167	BOLSAPLAST	TYVEK/FILM BAGS	300	650	1	84	37016867	17	1
MBT1166	BOLSAPLAST	TYVEK/FILM BAGS	400	580	1	84	37010679	56	5
MBT1165	BOLSAPLAST	TYVEK/FILM BAGS	320	560	1	84	37010679	57	2
MRF1059	BOLSAPLAST	PAPER/FILM GUSSET REELS	75x25	100	1	84	37010679	66	4
MRF1060	BOLSAPLAST	PAPER/FILM GUSSET REELS	100x40	100	1	84	37010679	60	2
MRF1061	BOLSAPLAST	PAPER/FILM GUSSET REELS	150x40	100	1	84	37010679	61	9
MRF1062	BOLSAPLAST	PAPER/FILM GUSSET REELS	200x60	100	1	84	37010679	62	6
MRF1063	BOLSAPLAST	PAPER/FILM GUSSET REELS	250x60	100	1	84	37010679	63	3
MRF1064	BOLSAPLAST	PAPER/FILM GUSSET REELS	300x80	100	1	84	37010679	64	0
MRF1065	BOLSAPLAST	PAPER/FILM GUSSET REELS	400x80	100	1	84	37010679	65	7
MRT1181	BOLSAPLAST	TYVEK/FILM FLAT REELS	60	70	1	84	37016867	13	3
MRT1171	BOLSAPLAST	TYVEK/FILM FLAT REELS	75	70	1	84	37010679	71	8
MRT1172	BOLSAPLAST	TYVEK/FILM FLAT REELS	100	70	1	84	37010679	72	5
MRT1174	BOLSAPLAST	TYVEK/FILM FLAT REELS	150	70	1	84	37010679	74	9
MRT1175	BOLSAPLAST	TYVEK/FILM FLAT REELS	200	70	1	84	37010679	75	6
MRT1176	BOLSAPLAST	TYVEK/FILM FLAT REELS	250	70	1	84	37010679	76	3
MRT1177	BOLSAPLAST	TYVEK/FILM FLAT REELS	300	70	1	84	37010679	77	0
MRT1180	BOLSAPLAST	TYVEK/FILM FLAT REELS	350	70	1	84	37010679	37	4
MRT1178	BOLSAPLAST	TYVEK/FILM FLAT REELS	400	70	1	84	37010679	78	7
MRT1179	BOLSAPLAST	TYVEK/FILM FLAT REELS	500	70	1	84	37010679	79	4
MBA1080	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	75	200	1	84	37010679	80	0
MBA1081	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	90	200	1	84	37010679	81	7
MBA1082	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	90	230	1	84	37010679	82	4
MBA1084	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	100	240	1	84	37010679	84	8
MBA1085	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	130	250	1	84	37010679	85	5
MBA1086	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	130	330	1	84	37010679	86	2
MBA1087	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	140	280	1	84	37010679	87	9
MBA1088	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	200	330	1	84	37010679	88	6
MBA1089	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	250	400	1	84	37010679	89	3
MBA1090	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	300	390	1	84	37010679	90	9
MBA1091	BOLSAPLAST	PAPER/FILM SELFSEALING BAGS	300	450	1	84	37010679	91	6

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MBCOVER001	BOLSAPLAST	BOLSACOVER	200	420	1	84	37016867	06	5
MBCOVER002	BOLSAPLAST	BOLSACOVER	270	360	1	84	37016867	07	2
MBCOVER003	BOLSAPLAST	BOLSACOVER	270	450	1	84	37016867	08	9
MBCOVER004	BOLSAPLAST	BOLSACOVER	300	500	1	84	37016867	09	6
MBCOVER005	BOLSAPLAST	BOLSACOVER	400	520	1	84	37016867	10	2
MBCOVER006	BOLSAPLAST	BOLSACOVER	400	580	1	84	37016867	11	9
MBCOVER007	BOLSAPLAST	BOLSACOVER	500	600	1	84	37016867	12	6
MBCOVER008	BOLSAPLAST	BOLSACOVER	570	720	1	84	37016867	28	7
MCREPV50/0	BOLSAPLAST	BOLSACREPE GREEN	50	50	1	84	37010679	38	1
MCREPV60/0	BOLSAPLAST	BOLSACREPE GREEN	60	60	1	84	37010679	39	8
MCREPV75/0	BOLSAPLAST	BOLSACREPE GREEN	75	75	1	84	37010679	50	3
MCREPV90/0	BOLSAPLAST	BOLSACREPE GREEN	90	90	1	84	37010679	55	8
MCREPV100/0	BOLSAPLAST	BOLSACREPE GREEN	100	100	1	84	37010679	58	9
MCREPV120/0	BOLSAPLAST	BOLSACREPE GREEN	120	120	1	84	37010679	59	6