

TECHNICAL DATA

Silicone external breast prostheses Maxima

Poznań 2018-2019-2020-2021-2022-2023

1. Technical requirements

1.1. General requirements

1.1.1. External breast prostheses should fulfill the technical requirements described below.

1.2. Basic parameters and sizes

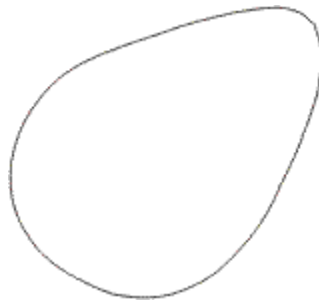
1.2.1. The breast prostheses are produced in following sizes corresponding to the tables 1,2,3,4.

Breast prosthesis Standard

Symmetrical tear drop shaped breast prosthesis suiting any kind of breast. The extension is placed under the arm.

Table 1

	Model	Producer's size	European size
Standard	4001, 4001 N, 4001 W, 4001 L	000	40
		00	45
		0	50
		1	55
		2	60
		3	65
		4	70
		5	75
		6	80
		7	85
		8	90
		9	95
		10	100
		11	105
		12	110
		13	115
		14	120
15	125		
16	130		
		17	135



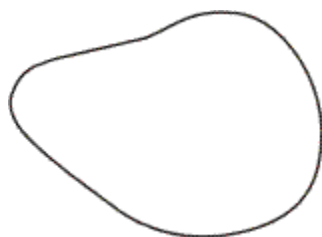
III. 1 Breast prosthesis Standard 4001

Breast prosthesis Asymmetric 1

Asymmetrical shaped breast prosthesis suiting any kind of breast. More ergonomic than the Standard (Ref. 4001) thanks to its extension at the top.

Table 2

	Model	Producer's size	European size
Asymmetric 1	6003	00	45
		0	50
		1	55
		2	60
		3	65
		4	70
		5	75
		6	80
		7	85
		8	90
		9	95
		10	100
		11	105
		12	110
		13	115
		14	120
		16	130
		17	135



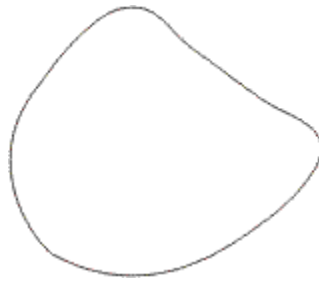
III.2 Breast prosthesis Asymmetric 1 (6003)

Breast prosthesis Asymmetric 2

Asymmetrical shaped breast prosthesis. The extensions of this model, oriented under the arm and at the top, fit the body shape perfectly.

Table 3

	Model	Producer's size	European size
Asymmetric 2	7004, 7004 N, 7004 L	0	50
		1	55
		2	60
		3	65
		4	70
		5	75
		6	80
		7	85
		8	90
		9	95
		10	100
		11	105
		12	110
		13	115
		14	120
		15	125
			16
	17	135	



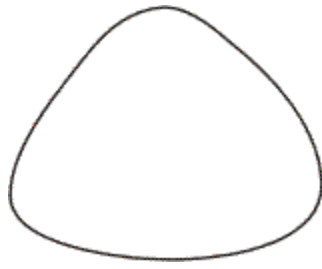
Ill. 3 Breast prosthesis Asymmetric 2 (7004)

Breast prosthesis Triangular

Symmetrical triangular shaped breast prosthesis. With a wide base this prosthesis is recommended for women with large chest and a flat bust.

Table 4

	Model	Producer's size	European size
Triangular	8005, 8005 N, 8005 L	0	50
		1	55
		2	60
		3	65
		4	70
		5	75
		6	80
		7	85
		8	90
		9	95
		10	100
		11	105
		12	110
		13	115
		14	120
		15	125
			16
	17	135	



Ill. 4 Breast prosthesis Triangular (8005)

1.2.2: The weight should be in concordance with the following tables:

Standard

Table 5

	Model	Size	Weight
Standard	4001, 4001 N, 4001 W	000	60 g
		00	79 g
		0	98 g
		1	110 g
		2	145 g
		3	186 g
		4	225 g
		5	300 g
		6	336 g
		7	400 g
		8	460 g
		9	510 g
		1	560 g
		11	620 g
		12	680 g
		13	730 g
		14	830 g
15	900 g		
16	960 g		

Standard Light

Table 6

	Model	Size	Weight
Standard	4001 L	000	45 g
		00	59 g
		0	72 g
		1	91 g
		2	120g
		3	152g
		4	182 g
		5	225 g
		6	258 g
		7	310 g
		8	350 g
		9	377 g
		10	414 g
		11	456 g
		12	497 g
		13	538 g
		14	623 g
15	665 g		
16	700 g		

Asymmetric 1

Table 7

	Model	Size	Weight
Asymmetric 1	6003	00	123 g
		0	133 g
		1	157 g
		2	177 g
		3	216 g
		4	246 g
		5	280 g
		6	324 g
		7	400 g
		8	468 g
		9	559 g
		10	609 g
		11	640 g
		12	713 g
		13	775 g
		14	830 g
		15	880 g
16	930 g		

Asymmetric 1 Light

Table 8

	Model	Size	Weight
Asymmetric 1	6003 L	00	91 g
		0	99 g
		1	117 g
		2	131 g
		3	160 g
		4	182 g
		5	208 g
		6	240 g
		7	296 g
		8	347 g
		9	414 g
		10	454 g
		11	474 g
		12	528 g
		13	574 g
		14	614 g
		15	651 g
16	688 g		

Asymmetric 2

Table 9

	Model	Size	Weight
Asymmetric 2	7004, 7004 N	0	91 g
		1	107 g
		2	132 g
		3	173 g
		4	223 g
		5	263 g
		6	305 g
		7	369 g
		8	470 g
		9	540 g
		10	610 g
		11	690 g
		12	760 g
		13	830 g
		14	880 g
		15	900 g
		16	920 g

Asymmetric 2 Light

Table 10

	Model	Size	Weight
Asymmetric 2	7004 L	0	67 g
		1	79 g
		2	98 g
		3	128g
		4	165 g
		5	195 g
		6	226 g
		7	273 g
		8	348 g
		9	400 g
		10	452 g
		11	510 g
		12	562 g
		13	615 g
		14	651 g
		15	700 g
		16	720 g

Triangular

Table 11

	Model	Size	Weight
Triangular	8005, 8005 N	00	80 g
		0	100g
		1	130 g
		2	160 g
		3	195 g
		4	215 g
		5	260 g
		6	315 g
		7	370 g
		8	470 g
		9	525 g
		10	610 g
		11	655 g
		12	695 g
		13	735 g
		14	790 g
		15	820 g
16	850 g		

Triangular Light

Table 12

	Model	Типоразмер	Weight
Triangular	8005 L	0	70 g
		1	101 g
		2	125 g
		3	152 g
		4	168 g
		5	203 g
		6	246 g
		7	289 g
		8	367 g
		9	410 g
		10	476 g
		11	511 g
		12	542 g
		13	573 g
		14	616 g
		15	640 g
		16	663 g

1.2.3. Basic parameters should be in concordance to the tables.

1.3. Basic parameters and characteristics.

1.3.1. Breast prostheses are manufactured with the raw materials show in Table 13.

Table 13

4001, 4001 L, 4001 N, 4001 W	silicone, thermoplastic polyurethane
6003	silicone, thermoplastic polyurethane
7004, 7004 L, 7004 N,	silicone, thermoplastic polyurethane
8005, 8005 L, 8005 N	silicone, thermoplastic polyurethane

1.3.2. The prostheses are not sterilized and are not sterile.

1.3.3. The prostheses should be produced only of the first quality.

1.3.4. The external appearance is evaluated under observation on the special desk.

1.3.5. Evaluation of the weight: the difference can be $\pm 10\%$.

1.3.6. All silicone should be placed in the impermeable film pocket. No signs, damages, broken film could be observed.

1.3.7. Prostheses should be weatherproof during transportation.

1.3.8. Storage time is not less than 5 years.

1.4. Completeness

1.4.1. Each set includes:

- breast prosthesis – 1 piece
- carton box – 1 piece
- plastic mould – 1 piece
- instruction of use – 1 piece

1.5 Marking

1.5.1. Producer's name, trade Mark and producer's address is printed on the carton box.

1.5.2. Name of product, producer's size and euro pean size is printed on the label sticked to the carton box.

1.6. Packing

1.6.1. Each prosthesis should be packed into carton box.

1.6.2. To protect the prosthesis each prosthesis should be placed in plastic mould.

1.6.3. Quantity in each carton box- 1 piece.

2. Admittance's rules.

2.1. Each prosthesis should be admitted individually.

2.2. Sequence and range of the examinations should be in concordance with table 14.

2.2.1. Periodic examination of quality should concern the prostheses which passed successfully the initial examinations and are packed for shipment.

Table 14

Name of test	Point's number		Quantity of items	
	Technical conditions	Test's method	initial	periodic
Check of carton	1.6.	3.4.	all	all
Check of marking	1.5.	3.4.	all	all
Check of completeness	1.4.	3.4.	all	all
Check of weight	1.2.2.	3.2.	all	all
Check of defect	1.3.6.	3.5.	all	all
Description of quality's class	1.3.3	3.5.	all	all

3. Testing methods

All test should be made in room temperature.

Scale is needed for examination.

Examination can be done at once after the process of production is finished.

3.1. Compatibility of the prostheses with the technical requirements/ documents is made by comparison with the documentation.

3.2. Weight is checked by using a scale.

3.3. The raw materials are checked during the delivery and admittance of the raw materials.

3.4. Quality and damages are checked with eyes in good light conditions.

3.5. Completeness, marking, packing is checked with eyes by comparison with the documents.

4. Transport and storage

4.1. All roofed means of transport can be used for transport. The general transport's requirements should be respected.

4.2. The prostheses should be storage in individual carton boxes in room temperature, minimum 1 m distance of the heating sources, humidity not more than 70%.
The stock should protect the prostheses against the mechanical damages, direct sun emission and soil.

5. Instruction for use.

5.1. The prostheses should be used in concordance with the instruction of use.

5.2. Instruction of use is always put into carton box.

6. Product's warranty

6.1. Producer warranties the compatibility of the product with the technical requirements provided that the proper conditions of using, transport and storage are kept.

6.2. Warranty period for shelve life is 5 years since date of production.