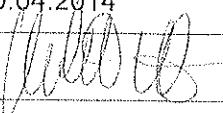


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Appendix to  
Declaration of Conformity Amoena Breast Prosthesis  
Revision 24

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Amoena Medizin-Orthopädie-Technik GmbH  
Kapellenweg 35 D-83064 Raasdorf  
Tel 08035/871-0 Fax 08035/871-549

|            |                                                                                   |            |                                                                                     |
|------------|-----------------------------------------------------------------------------------|------------|-------------------------------------------------------------------------------------|
| Issued:    | Helmut Wild<br>Global Head of<br>Product Development<br>Silicones                 | Approved:  | Rainer Pfeffermann<br>Global Head of<br>Operations Silicones<br>and Logistics       |
| Date:      | 30.04.2014                                                                        | Date:      | 30.04.2014                                                                          |
| Signature: |  | Signature: |  |

| product name                       | segment | article number | originally CE-marked |
|------------------------------------|---------|----------------|----------------------|
| Amoena Balance 1C                  | Balance | 275 A          | 10/1997              |
| Amoena Balance 1O                  | Balance | 259 A          | 12/1995              |
| Amoena Balance 2C                  | Balance | 275 B          | 10/1997              |
| Amoena Balance 2O                  | Balance | 259 B          | 12/1995              |
| Amoena Balance 1D                  | Balance | 271A           | 25.03.2009           |
| Amoena Balance 2D                  | Balance | 271B           | 25.03.2009           |
| Amoena Balance Contact 2D          | Balance | 272B           | 25.03.2009           |
| Amoena Balance Individual Light 2D | Balance | 273B           | 25.03.2009           |
| Amoena Balance Contact 2O          | Balance | 252B           | 25.03.2009           |
| Amoena Balance 2V                  | Balance | 241            | 25.03.2009           |
| Amoena Balance Contact 2V          | Balance | 242            | 25.03.2009           |
| Amoena Balance Contact Delta       | Balance | 284B           | 14.11.2012           |
| Amoena Balance Contact Oval        | Balance | 287B           | 14.11.2012           |
| Amoena Balance Contact Varia       | Balance | 286            | 14.11.2012           |
| Amoena Balance Delta               | Balance | 282A<br>282B   | 14.11.2012           |
| Amoena Balance Oval                | Balance | 283A<br>283B   | 14.11.2012           |
| Amoena Balance Varia               | Balance | 285            | 14.11.2012           |
| Amoena Basic                       | Basic   | 290            | 31.08.2010           |
| Amoena Basic Light                 | Basic   | 292            | 31.08.2010           |
| Amoena Contact 1S                  | Contact | 384            | 01.04.2010           |
| Amoena Contact 2S                  | Contact | 381            | 08.02.2008           |
| Amoena Contact 2A                  | Contact | 383            | 01.04.2010           |
| Amoena Contact 3E                  | Contact | 386            | 01.04.2010           |
| Amoena Contact 3S                  | Contact | 382            | 08.02.2008           |
| Amoena Contact Light 2S            | Contact | 380            | 08.02.2008           |
| Amoena Contact Light 3S            | Contact | 385            | 01.04.2010           |
| Amoena Energy Light 3U             | Energy  | 340            | 31.08.2010           |
| Amoena Energy Light 2U             | Energy  | 341            | 31.08.2010           |
| Amoena Energy Light 2S             | Energy  | 342            | 20.04.2011           |
| Amoena Energy 2U                   | Energy  | 347            | 20.04.2011           |
| Amoena Energy 1S                   | Energy  | 349            | 27.10.2011           |



**sis** **System Medizin - Orthopädie - Technische Geräte**  
Kopplertweg 38 · D-63064 Frankfurt  
Tel. 08035/871 · 0 · Fax 08035/871-54

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Appendix to  
Declaration of Conformity Amoena Breast Prosthesis  
Revision 24

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Klinik Medizin-Orthopädie-Technik GmbH  
Kneipenweg 36 · D-85064 Raubling  
Tel. 08035/871 0 Fax 08035/871 541

| product name               | old product name<br>(valid until 31.12.2006) | article number | originally<br>CE-marked | production / sales<br>discontinued |
|----------------------------|----------------------------------------------|----------------|-------------------------|------------------------------------|
| Amoena Balance 1T          | Balance Part Top                             | 277 A          | 10/1997                 | 04/2010                            |
| Amoena Balance 2D          | Balance Delta                                | 271            | 10/1997                 | 04/2009                            |
| Amoena Balance 2T          | Balance Part Top                             | 277 B          | 10/1997                 | 04/2010                            |
| Amoena Balance Contact 1C  | Balance Part Bottom Contact                  | 276 A          | 10/1997                 | 04/2010                            |
| Amoena Balance Contact 1T  | Balance Part Top Contact                     | 278 A          | 10/1997                 | 04/2010                            |
| Amoena Balance Contact 2C  | Balance Part Bottom Contact                  | 276 B          | 10/1997                 | 04/2010                            |
| Amoena Balance Contact 2D  | Balance Delta Contact                        | 272            | 08.04.2005              | 04/2009                            |
| Amoena Balance Contact 2T  | Balance Part Top Contact                     | 278 B          | 10/1997                 | 04/2010                            |
| Amoena Climate Light 2A    | Classic Light Climate Control                | 358            | 01.03.2005              | 01/ 2011                           |
| Amoena Climate Light 2S    | Tria Light Climate Control                   | 458            | 23.03.2006              | 01/ 2011                           |
| Amoena Contact 1S          | Tresia Personally Contact                    | 653            | 23.08.2004              | discontinued                       |
| Amoena Contact 2A          | Classic Contact                              | 351            | 02/2001                 | discontinued                       |
| Amoena Contact 3E          | -                                            | 521            | 16.04.2007              | discontinued                       |
| Amoena Contact 3S          | Tria Contact                                 | 361            | 18.04.2000              | 01/2009                            |
| Amoena Contact Light 3S    | Tria Contact Light                           | 368            | 01.07.2002              | discontinued                       |
| Amoena Contact Plus 3S     | Tria Plus                                    | 265            | 12/1995                 | 12/2007                            |
| Amoena Essential 1S        | Tresia Personally                            | 643            | 01.10.2003              | discontinued                       |
| Amoena Individual 2A       | Classic Flow                                 | 359            | 13.02.2002              | 01/2009                            |
| Amoena Individual 3S       | Tria Flow                                    | 369            | 13.02.2002              | 01/2009                            |
| Amoena Individual Light 1S | Tresia                                       | 760            | 01.10.2003              | 01/2009                            |
| Amoena Individual Light 3A | Prema                                        | 720            | 01.10.2003              | 01/2009                            |
| Amoena Natura 2A           | Classic II                                   | 355            | 12/1995                 | discontinued                       |
| Amoena Natura 3A           | Personally                                   | 651            | 01.10.2003              | 04/2009                            |
| Amoena Natura 3E           | Natura                                       | 661            | 01.10.2003              | 12/2010                            |
| Amoena Natura 3S           | Tria II                                      | 362            | 12/1995                 | discontinued                       |
| Amoena Natura Light 2A     | Classic Light                                | 354            | 09/1996                 | discontinued                       |
| Amoena Natura Light 2S     | -                                            | 447            | 02/2007                 | discontinued                       |
| Amoena Natura Light 3S     | Tria Light                                   | 366            | 18.04.2000              | discontinued                       |
| Amoena Priform             | Priform                                      | 206            | 12/1995                 | 12/2010                            |
| Classic Contact            | -                                            | 350            | 11/1996                 | 02/2001                            |
| Classic Plus               | -                                            | 352            | 12/1995                 | 12/2007                            |
| Contour oval               | -                                            | A260           | 12/1995                 | 12/2007                            |
| Discrene Asymmetric        | -                                            | 9640           | 25.11.2002              | 12/2007                            |
| Discrene Teardrop          | -                                            | 9530           | 25.11.2002              | 12/2007                            |
| Discrene Triangle          | -                                            | 9560           | 25.11.2002              | 12/2007                            |
| Ella                       | -                                            | 303, 304, 307  | 12/1995                 | 09/2002                            |
| Natura                     | -                                            | 242            | 12/1995                 | 12/2000                            |
| Tria A/B                   | -                                            | 364            | 12/1995                 | -                                  |
| Tria C/D                   | -                                            | 368            | 12/1995                 | -                                  |
| Amoena Swimform            | Tria Swimform                                | 129            | 01.10.2003              | 29.04.2011                         |

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Issued: Iris Vetter

19.09.2014

| BRA COLLECTION RAUBILING/Valletta Top |                                                                                        |                                                                                  |                                                      |                          |               |
|---------------------------------------|----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|------------------------------------------------------|--------------------------|---------------|
| Amoena Bras                           | Item number/ Color                                                                     | Sizes                                                                            | originally CE-marked                                 | *NOS/**OTS               | Segment       |
| Alison                                | 2061: white                                                                            | XS S M L XL                                                                      | 22.03.2013                                           | NOS                      | Recovery Care |
| Annette WB                            | 1087: black/nude                                                                       | 75-110 B C D; 80-105 E; 80-100 F<br>80-90 G                                      | 19.09.2014                                           | NOS                      | Everyday      |
| Angela SB                             | 0766: white                                                                            | 70 - 90 AA; 75 - 95 A B<br>75 - 90 C                                             | 27.01.2011                                           | NOS                      | Everyday      |
| Barbara WB                            | 0457 nude<br>1077: black                                                               | 70 - 90 A B C<br>70 - 85 D                                                       | 15.01.2014<br>19.09.2014                             | NOS<br>OTS               | Everyday      |
| Brigitte SB                           | 0478: lavender<br>0476: pearl                                                          | 70 - 80 A<br>70 - 90 B C D                                                       | 15.01.2014<br>15.01.2014                             | OTS                      | Seduction     |
| Brigitte WB                           | 0481: lavender<br>0479: pearl                                                          | 70 - 80 A; 70 - 95 B C<br>75 - 100 D E F                                         | 15.01.2014<br>15.01.2014                             | OTS                      | Seduction     |
| Brigitte SB-Top                       | 0483: lavender<br>0482: pearl                                                          | 70 - 80 A<br>70 - 90 B C D                                                       | 15.01.2014<br>15.01.2014                             | OTS                      | Seduction     |
| Carmen                                | 0700: white                                                                            | 80 - 110 A; 75 - 110 B C D<br>80 - 105 E; 85 - 105 F                             | 26.02.2007                                           | NOS                      | Everyday      |
| Charlene SB                           | 0489: light blue<br>0488: white                                                        | 70 - 80 A; 70 - 90 B C D                                                         | 15.01.2014<br>15.01.2014                             | OTS                      | Seduction     |
| Charlene WB                           | 0491: light blue<br>0490: white                                                        | 70 - 80 A; 70 - 95 B C<br>75 - 100 D E F                                         | 15.01.2014<br>15.01.2014                             | OTS                      | Seduction     |
| Charlene SB-Top                       | 0493: light blue<br>0492: white                                                        | 70 - 80 A; 70 - 90 B C D                                                         | 15.01.2014<br>15.01.2014                             | OTS                      | Seduction     |
| Colette SB                            | 1094: off-white<br>1095: dark grey                                                     | 70 - 80 A; 70-90 B C D                                                           | 19.09.2014                                           | OTS                      | Seduction     |
| Colette WB                            | 1096: off-white<br>1097: dark grey                                                     | 70 - 80 A; 70-95 B C;<br>75-100 D E                                              | 19.09.2014                                           | OTS                      | Seduction     |
| Colette SB Nuiset                     | 1098: off-white<br>1099: dark grey                                                     | 80 A; 70 - 90 B C<br>75 - 80 A; 75 - 90 B; 70 - 90 C,<br>80 - 90 D               | 19.09.2014                                           | OTS                      | Seduction     |
| Dana SB                               | 0750: black<br>0751: off-white<br>0862: white                                          | 70 - 90 AA; 70 - 100 A B C<br>75 - 95 D E                                        | 0750, 0751: 27.01.2011<br>0862: 01.02.2012           | NOS                      | Everyday      |
| Danielle SB                           | 1114: plum                                                                             | 70 - 80 A; 70 - 90 B C D                                                         | 19.09.2014                                           | OTS                      | Seduction     |
| Danielle WB                           | 1115: plum                                                                             | 70 - 80 A; 70-95 B C;<br>75 - 100 D E F                                          | 19.09.2014                                           | OTS                      | Seduction     |
| Danielle SB Top                       | 1116: plum                                                                             | 70 - 80 A; 70 - 90 B C D                                                         | 19.09.2014                                           | OTS                      | Seduction     |
| Frances                               | 2128: white, nude                                                                      | XS S M L XL                                                                      | 26.09.2007                                           | NOS                      | Recovery Care |
| Hannah SB                             | 2160: white                                                                            | XS S M L XL                                                                      | 22.03.2013                                           | NOS                      | Recovery Care |
| Hannah                                | 2860: white                                                                            | XS S M L XL 2XL                                                                  | 01.02.2009                                           | NOS                      | Recovery Care |
| Isabel                                | 2118: white, black                                                                     | 70 - 85 AA; 70 - 100 A;<br>70 - 105 B C; 70 - 95 D; 75 - 95 E                    | 26.09.2007                                           | NOS                      | Everyday      |
| Isadora SB                            | 0947 white<br>0948 nude                                                                | 75 - 115 A; 70 - 110 B C D<br>70 - 100 E F G                                     | 01.08.2013                                           | NOS                      | Everyday      |
| Jasmin                                | 0900: white                                                                            | 70 - 90 AA A B<br>75 - 90 C                                                      | 1995                                                 | NOS                      | Everyday      |
| Judy SB                               | 1083: off-white/light earth                                                            | 70-90 A B; 75-90 C D                                                             | 19.09.2014                                           | OTS                      | Everyday      |
| Judy WB                               | 1084: off-white/light earth                                                            | 70-95 B; 75-95 C D                                                               | 19.09.2014                                           | OTS                      | Everyday      |
| Judy SH                               | 1085: off-white/light earth                                                            | 36-46                                                                            | 19.09.2014                                           | OTS                      | Everyday      |
| Johanne SB                            | 1104: black<br>1105: red amber                                                         | 70-80 A; 70-90 B C D                                                             | 19.09.2014                                           | OTS                      | Seduction     |
| Johanne WB                            | 1106: black<br>1107: red amber                                                         | 70-80 A; 70-95 B C;<br>75-100 D E                                                | 19.09.2014                                           | OTS                      | Seduction     |
| Johanne SB Body                       | 1108: black<br>1109: red amber                                                         | 80 A; 70-90 B C D<br>75 - 80 A; 70-90 B C D                                      | 19.09.2014                                           | OTS                      | Seduction     |
| Karla SB                              | 0427: off-white/hougal<br>0426: peach/apricot<br>1057: white<br>1056: Dark Berry/Grape | 70 - 95 A B<br>75 - 95 C D<br>70 - 95 A B; 75 - 95 D C<br>70-95 A B; 75 - 95 C D | 15.01.2014<br>15.01.2014<br>26.08.2014<br>19.09.2014 | OTS<br>OTS<br>NOS<br>OTS | Everyday      |

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| BRA COLLECTION RAUBLING/Valletta Top |                            |                             |                         |            |               |
|--------------------------------------|----------------------------|-----------------------------|-------------------------|------------|---------------|
| Amoena Bras                          | Item number/ Color         | Sizes                       | originally CE-marked    | *NOS/**OTS | Segment       |
| Karla WB                             | 0429: off-white/nougat     | 70 - 95 B C; 75 - 95 D      | 15.01.2014              | OTS        | Everyday      |
|                                      | 0428: peach/apricot        | 75 - 90 E                   | 15.01.2014              | OTS        |               |
|                                      | 1059: white                | 70-95 B C, 75-95 D, 75-90 E | 26.08.2014              | NOS        |               |
|                                      | 1058: Dark Berry/Grape     | 70-95 B C, 75-95 D, 75-90 E | 19.09.2014              | OTS        |               |
| Karla SH                             | 0432: off-white/nougat     | 70 - 90 A; 75 - 90 B C      | 15.01.2014              | OTS        | Everyday      |
|                                      | 0431: peach/apricot        |                             | 15.01.2014              | OTS        |               |
|                                      | 1060: dark berry/grape     |                             | 19.09.2014              | OTS        |               |
| Lara Comfort 3D                      | 0437: nude                 |                             | 15.01.2014              | NOS        | Everyday      |
|                                      | 0436: black                | 70 - 100 A B C D E          | 15.01.2014              | NOS        |               |
| Lara Comfort SB                      | 0435: coral red            | 70 - 100 B C D E            | 15.01.2014              | OTS        | Everyday      |
|                                      | 0956: nude                 |                             | 0956 + 0955: 29.08.2013 | NOS        |               |
|                                      | 0955: black                |                             |                         | NOS        |               |
| Lara Lace SB                         | 0453: salmon               | 70 - 95 AA A B C D          | 15.01.2014              | OTS        | Everyday      |
|                                      | 0452: white/nude           |                             | 15.01.2014              | OTS        |               |
| Lara Lace Desire SB                  | 1067 Raspberry/dark berry  | 70-95 AA A B C D            | 19.09.2014              | OTS        | Everyday      |
|                                      | 1068: grey/silver          |                             |                         | OTS        |               |
| Lara Jacquard SB                     | 1071 Rose                  | 70-95 AA, A, B, C, D        | 19.09.2014              | OTS        | Everyday      |
| Lara Satin SB                        | 1073: light earth          | 70-95 AA A B C D            | 19.09.2014              | OTS        | Everyday      |
|                                      | 1074: blackberry           |                             |                         |            |               |
| Lara SB                              | 0674: nude                 | 75-90 AA; 70-90 A,B,C       | 0674, 0675: 26.09.2007  | NOS        | Everyday      |
|                                      | 0675: black                | 75-90 D                     |                         | NOS        |               |
|                                      | 0752: off-white            |                             | 0752: 01.03.2010        | NOS        |               |
| Lina SB                              | 0439: coral red            | 70-95 A B C D               | 15.01.2014              | OTS        | Everyday      |
|                                      | 0438: ivory                | 75-90 E                     | 15.01.2014              | NOS        |               |
| Lina WB                              | 0444: coral red            | 70-95 A B C D               | 15.01.2014              | OTS        | Everyday      |
|                                      | 0443: ivory                | 75-90 E                     | 15.01.2014              | NOS        |               |
| Luana SB                             | 0498: rose/pink            | 70 - 80 A; 70-90 B C D      | 15.01.2014              | OTS        | Seduction     |
| Luana WB                             | 0499: rose/pink            | 70 - 80 A; 70 - 95 B C      | 15.01.2014              | OTS        | Seduction     |
|                                      |                            | 75 - 100 D E F              |                         |            |               |
| Luana Nuiet                          | 0501: rose/pink            | 70 - 80 A; 70 - 90 B C D    | 15.01.2014              | OTS        | Seduction     |
| Lucia WB                             | 0456: white                | 70 - 90 AA A B C D          | 15.01.2014              | NOS        | Everyday      |
|                                      |                            | 75 - 85 E                   |                         |            |               |
| Magdalena SB                         | 0463: nude                 | 75 - 110 B C D E F          | 15.01.2014              | NOS        | Everyday      |
|                                      | 1078: black                |                             | 19.09.2014              | NOS        |               |
| Magdalena Print SB                   | 1079: light earth          | 75-110 B C D E F            | 19.09.2014              | OTS        | Everyday      |
| Marisa SB                            | 0767: white                | 80 - 110 A B C D            | 15.01.2014              | NOS        | Everyday      |
|                                      |                            | 80 - 105 E                  |                         |            |               |
| Michelle                             | 2105: white                | XS S M L XL XXL             | 2003                    | NOS        | Recovery Care |
| Mona SB                              | 0606: white                | 70 - 95 AA A B              | 0606: 27.10.2004        | NOS        | Everyday      |
|                                      | 0568: champ                | 75 - 90 C D                 | 0568: 29.06.2001        | NOS        |               |
|                                      | 0591: black                | 75 - 85 E                   | 0591: 31.10.2003        | NOS        |               |
|                                      | 0614: cognac               |                             | 0614: 04.04.2005        | NOS        |               |
|                                      | 1092: dark plum            |                             | 1092: 19.09.2014        | OTS        |               |
| Mona WB                              | 0946: champagne            | 70 - 95 A; 75 - 95 B C D    | 0946: 01.08.2013        | NOS        | Everyday      |
|                                      | 0945: black                | 75 - 90 E                   | 0945: 01.08.2013        | NOS        |               |
| Natalie SB                           | 0584: champagne            | 75 - 95 B C D               | 2001                    | NOS        | Everyday      |
| Nora                                 | 0555: white                | 80 - 100 A B C D            | 0555: 29.06.2001        | NOS        | Everyday      |
|                                      | 0557: black                |                             | 0557: 26.09.2007        | NOS        |               |
| Pauline SB                           | 0448: blue/off-white       | 70 - 90 A B                 | 15.01.2014              | OTS        | Everyday      |
|                                      |                            | 75 - 90 C D                 |                         |            |               |
| Pauline WB                           | 0449: blue/off-white       | 70 - 95 B                   | 15.01.2014              | OTS        | Everyday      |
|                                      |                            | 75 - 95 C D                 |                         |            |               |
| Pauline SH                           | 0450: blue/off-white       | 36 - 46                     | 15.01.2014              | OTS        | Everyday      |
| Performance                          | 0654: white                | 70 - 95 AA A B C D E        | 0654: 13.11.2008        | NOS        | Everyday      |
|                                      | 0658: black                |                             | 0658: 26.09.2007        | NOS        |               |
| Power SB Medium Support              | 1210: passionate pink/grey | 70 - 95 AA A B C D E        | 19.09.2014              | OTS        | Active Wear   |
| Rebecca SB                           | 0806: white                | 80 - 110 A; 75 - 110 B C D  | 0806: 27.01.2011        | NOS        | Everyday      |
|                                      | 0969: black                | 80 - 105 E; 85 - 105 F      | 0969: 22.03.2013        | NOS        |               |
| Rebecca WB                           | 0807: white                | 75 - 110 B C D              | 0807: 27.01.2011        | NOS        | Everyday      |
|                                      | 0972: black                | 80 - 105 E                  | 0972: 22.03.2013        | NOS        |               |



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| BRA COLLECTION RAUBLING/Valletta Top |                           |                                                       |                                          |                   |               |
|--------------------------------------|---------------------------|-------------------------------------------------------|------------------------------------------|-------------------|---------------|
| Amoena Bras                          | Item number/Color         | Sizes                                                 | originally CE-marked                     | *NOS/**OTS        | Segment       |
| Rita SB                              | 2004: all colors          | 75 - 100 A B C<br>75 - 105 D<br>80 - 105 E            | Nude: 2007<br>White: 2008<br>Black: 2012 | NOS<br>NOS<br>NOS | Everyday      |
| Rosalie SB                           | 0870: white<br>0871: nude | 75 - 105 A B C D E F                                  | 01.02.2012                               | NOS<br>NOS        | Everyday      |
| Ruth SB                              | 0872: nude<br>0873: white | 70 - 105 AA A B; 70 - 100 C<br>70 - 95 D E; 70 - 90 F | 01.02.2012                               | NOS<br>NOS        | Everyday      |
| Sandra                               | 0622: white               | S M L XL 2XL 3XL 4XL                                  | 15.12.2005                               | NOS               | Recovery Care |
| Silvia                               | 0998: white<br>0999: nude | 70 - 90 AA; 70 - 110 A B C D E F                      | 02.07.2013                               | NOS               | Everyday      |
| Valletta Top                         | 1209: passionate pink     | 38 - 54                                               | 19.09.2014                               | OTS               | Leisure Wear  |
| Theraport                            | 2161: white               | S M L XL 2XL                                          | 22.03.2013                               | NOS               | Recovery Care |

\* NOS = never out of stock

\*\* OTS = one time shot