

ID: REC-1140
Title: Declaration of Conformity Rigid Trial Lenses
Date: 2026-06-11

CE Declaration of Conformity

Multilens AB, Skinnefjällsv. 1 43525 Mölnlycke Sweden, being the manufacturer declares under sole responsibility that the below medical device is in conformity with the Medical Device Regulation (EU) 2017/745 (MDR).

| | | | | |
|--|---|------------------------|------------------|--|
| Product name: | Rigid Trial Lenses (listed in detailed in appendix) | | | |
| Product Classification: | Class I | | | |
| Single Registration Number (Eudamed): | SE-MF 000002792 | | | |
| Common Specifications applied: | Not applicable | | | |
| Conformity assessment procedure: | Self certification | | | |
| Basic UDI-DI: | Product types | Material | Model ref | Basic UDI-DI |
| | Corneal rigid gas permeable (RGP) trial lens | Optimum Extra Red | cornealTrialOE | 731686cornealTrialOEVQ 731686cornealTrialOEMTSJZ |
| | | Boston ES Blue | cornealTrialBES | 731686cornealTrialBES4W 731686cornealTrialBEMTSEJ |
| | Corneo-scleral rigid gas permeable (RGP) trial lens | Optimum Extra Ice Blue | scleralTrialOE | 731686scleralTrialOEXY 731686scleralTrialOEMTSQD |
| Intended purpose: Reusable rigid gas permeable trial lens for multipatient use to be used for fitting of contact lenses. | | | | |

Place and Date: Mölnlycke, 2026-06-11

Place and Date: Mölnlycke, 2026-06-11

Signature:

Marie Leander

Marie Leander (Jun 11, 2026 14:48:31 GMT+2)

Signature:

Fredrik Pamp

Fredrik Pamp (Jun 11, 2026 16:27:08 GMT+2)

Name and

Function

Marie Leander, PRRC

Name and

Function

Fredrik Pamp, CEO

Signed on behalf of Multilens AB

Appendix to Declaration of Conformity

Corneal rigid gas permeable (RGP) trial lens, Optimum Extra Red

Table 1. Made to order trial lenses, basic UDI-DI 731686cornealTrialOEVO.

| Design | Material | Colour | Art No |
|------------|---------------|--------|--------|
| Rose K2 KC | Optimum Extra | Red | N70125 |
| Rose K2 NC | Optimum Extra | Red | N70126 |
| Rose K2 IC | Optimum Extra | Red | N70127 |
| Rose K2 PG | Optimum Extra | Red | N70128 |

Table 2. Stock trial lenses, basic UDI-DI 731686cornealTrialOEMTSJZ.

| Design | Material | Colour | BC | Dia | Power | Art No |
|------------|---------------|--------|--------|-----|-------|--------|
| Rose K2 KC | Optimum Extra | Red | 5,1 | 8,5 | 23,0 | N70200 |
| | | | 5,2 | 8,5 | 22,0 | N70201 |
| | | | 5,3 | 8,5 | 21,0 | N70202 |
| | | | 5,4 | 8,6 | 20,0 | N70203 |
| | | | 5,5 | 8,6 | 19,0 | N70204 |
| | | | 5,6 | 8,6 | 18,0 | N70205 |
| | | | 5,7 | 8,7 | 17,0 | N70206 |
| | | | 5,8 | 8,7 | 16,0 | N70207 |
| | | | 5,9 | 8,7 | 15,0 | N70208 |
| | | | 6,0 | 8,7 | 14,0 | N70209 |
| | | | 6,1 | 8,7 | 13,0 | N70210 |
| | | | 6,2 | 8,7 | 12,0 | N70211 |
| | | | 6,3 | 8,7 | 11,0 | N70212 |
| | | | 6,4 | 8,7 | 10,0 | N70213 |
| | | | 6,5 | 8,7 | -9,0 | N70214 |
| | | | 6,6 | 8,7 | -8,0 | N70215 |
| | | | 6,7 | 8,8 | -7,0 | N70216 |
| | | | 6,8 | 8,8 | -6,0 | N70217 |
| | | | 6,9 | 8,9 | -5,0 | N70218 |
| | | | 7,0 | 8,9 | -4,0 | N70219 |
| | | | 7,1 | 9,0 | -3,0 | N70220 |
| | | | 7,2 | 9,0 | -3,0 | N70221 |
| | | | 7,3 | 9,1 | -3,0 | N70222 |
| | | | 7,4 | 9,1 | -2,0 | N70223 |
| | | | 7,5 | 9,2 | -2,0 | N70224 |
| | | | 7,6 | 9,2 | -2,0 | N70225 |
| Rose K2 NC | Optimum Extra | Red | 4,6 | 8,1 | 28,0 | N70226 |
| | | | 4,8 | 8,2 | 26,0 | N70227 |
| | | | 5,0 | 8,2 | 24,0 | N70228 |
| | | | 5,1 | 8,3 | 23,0 | N70229 |
| | | | 5,2 | 8,3 | 22,0 | N70230 |
| | | | 5,3 | 8,3 | 21,0 | N70231 |
| | | | 5,4 | 8,3 | 20,0 | N70232 |
| 5,5 | 8,3 | 19,0 | N70233 | | | |

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| Design | Material | Colour | BC | Dia | Power | Art No |
|------------|---------------|--------|--------|------|-------|--------|
| | | | 5,6 | 8,3 | 18,0 | N70234 |
| | | | 5,7 | 8,3 | 17,0 | N70235 |
| | | | 5,8 | 8,3 | 16,0 | N70236 |
| | | | 5,9 | 8,3 | 15,0 | N70237 |
| | | | 6,0 | 8,3 | 14,0 | N70238 |
| | | | 6,1 | 8,4 | 13,0 | N70239 |
| | | | 6,2 | 8,4 | 12,0 | N70240 |
| | | | 6,3 | 8,4 | 11,0 | N70241 |
| | | | 6,4 | 8,5 | 10,0 | N70242 |
| | | | 6,5 | 8,5 | -9,0 | N70243 |
| | | | 6,6 | 8,6 | -8,0 | N70244 |
| | | | 6,7 | 8,6 | -7,0 | N70245 |
| | | | 6,8 | 8,7 | -6,0 | N70246 |
| | | | 6,9 | 8,7 | -5,0 | N70247 |
| | | | 7,0 | 8,8 | -4,0 | N70248 |
| 7,2 | 8,8 | -3,0 | N70249 | | | |
| 7,4 | 8,9 | -2,0 | N70250 | | | |
| Rose K2 PG | Optimum Extra | Red | 6,0 | 10,4 | 20,0 | N70251 |
| | | | 6,2 | 10,4 | 18,0 | N70252 |
| | | | 6,4 | 10,4 | 16,0 | N70253 |
| | | | 6,6 | 10,4 | 14,0 | N70254 |
| | | | 6,8 | 10,4 | 12,0 | N70255 |
| | | | 6,9 | 10,4 | 11,0 | N70256 |
| | | | 7,0 | 10,4 | 10,0 | N70257 |
| | | | 7,1 | 10,4 | -9,0 | N70258 |
| | | | 7,2 | 10,4 | -8,0 | N70259 |
| | | | 7,3 | 10,4 | -7,0 | N70260 |
| | | | 7,4 | 10,4 | -6,0 | N70261 |
| | | | 7,5 | 10,4 | -5,0 | N70262 |
| | | | 7,6 | 10,4 | -4,0 | N70263 |
| | | | 7,7 | 10,4 | -3,0 | N70264 |
| | | | 7,8 | 10,4 | -2,0 | N70265 |
| | | | 7,9 | 10,4 | -1,0 | N70266 |
| | | | 8,0 | 10,4 | 0,0 | N70267 |
| | | | 8,2 | 10,4 | 0,0 | N70268 |
| 8,4 | 10,4 | +1,0 | N70269 | | | |
| 8,6 | 10,4 | +1,0 | N70270 | | | |
| 8,8 | 10,4 | +2,0 | N70271 | | | |
| 9,0 | 10,4 | +2,0 | N70272 | | | |
| Rose K2 IC | Optimum Extra | Red | 6,0 | 11,2 | 20,0 | N70273 |
| | | | 6,2 | 11,2 | 18,0 | N70274 |
| | | | 6,4 | 11,2 | 16,0 | N70275 |
| | | | 6,6 | 11,2 | 14,0 | N70276 |
| | | | 6,8 | 11,2 | 12,0 | N70277 |
| | | | 7,0 | 11,2 | 10,0 | N70278 |
| | | | 7,1 | 11,2 | -9,0 | N70279 |
| | | | 7,2 | 11,2 | -8,0 | N70280 |
| 7,3 | 11,2 | -7,0 | N70281 | | | |

| Design | Material | Colour | BC | Dia | Power | Art No |
|--------|----------|--------|-----|------|-------|--------|
| | | | 7,4 | 11,2 | -6,0 | N70282 |
| | | | 7,5 | 11,2 | -5,0 | N70283 |
| | | | 7,6 | 11,2 | -4,0 | N70284 |
| | | | 7,7 | 11,2 | -3,0 | N70285 |
| | | | 7,8 | 11,2 | -2,0 | N70286 |
| | | | 7,9 | 11,2 | -1,0 | N70287 |
| | | | 8,0 | 11,2 | 0,0 | N70288 |
| | | | 8,2 | 11,2 | 0,0 | N70289 |
| | | | 8,4 | 11,2 | +1,0 | N70290 |

Corneal rigid gas permeable (RGP) trial lens, Boston ES Blue

Table 3. Made to order trial lenses, basic UDI-DI 731686cornealTrialBES4W.

| Design | Material | Colour | Art No |
|----------|-----------|--------|--------|
| A-design | Boston ES | Blue | N70112 |
| Envision | Boston ES | Blue | N70113 |

Table 4. Stock trial lenses, basic UDI-DI 731686cornealTrialBEMTSEJ.

| Design | Material | Colour | BC | Dia | Power | Art No |
|----------|-----------|--------|-----|-----|-------|--------|
| A-design | Boston ES | Blue | 7,4 | 9,8 | -3,0 | N70307 |
| | | | 7,5 | 9,8 | -3,0 | N70308 |
| | | | 7,6 | 9,8 | -3,0 | N70309 |
| | | | 7,7 | 9,8 | -3,0 | N70310 |
| | | | 7,8 | 9,8 | -3,0 | N70311 |
| | | | 7,9 | 9,8 | -3,0 | N70312 |
| | | | 8,0 | 9,8 | -3,0 | N70313 |
| | | | 8,1 | 9,8 | -3,0 | N70314 |
| | | | 8,2 | 9,8 | -3,0 | N70315 |
| | | | 7,5 | 9,8 | +3,0 | N70316 |
| | | | 7,6 | 9,6 | +3,0 | N70317 |
| | | | 7,7 | 9,6 | +3,0 | N70318 |
| | | | 7,8 | 9,6 | +3,0 | N70319 |
| | | | 8,0 | 9,6 | +3,0 | N70320 |
| Envision | Boston ES | Blue | 8,2 | 9,6 | +3,0 | N70321 |
| | | | 7,4 | 9,6 | -3,0 | N70322 |
| | | | 7,5 | 9,6 | -3,0 | N70323 |
| | | | 7,6 | 9,6 | -3,0 | N70324 |
| | | | 7,7 | 9,6 | -3,0 | N70325 |
| | | | 7,8 | 9,6 | -3,0 | N70326 |
| | | | 7,9 | 9,6 | -3,0 | N70327 |
| | | | 8,0 | 9,6 | -3,0 | N70328 |
| | | | 8,1 | 9,6 | -3,0 | N70329 |
| | | | 8,2 | 9,6 | -3,0 | N70330 |
| | | | 7,6 | 9,6 | +3,0 | N70331 |
| | | | 7,8 | 9,6 | +3,0 | N70332 |

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|--|--|--|-----|-----|------|--------|
| | | | 8,0 | 9,6 | +3,0 | N70333 |
| | | | 8,2 | 9,6 | +3,0 | N70334 |

Corneo-scleral rigid gas permeable (RGP) trial lens, Optimum Extra Ice Blue

Table 5. Made to order trial lenses, basic UDI-DI 731686scleralTrialOEXY.

| Design | Material | Colour | Art No |
|------------|---------------|----------|--------|
| Rose K2 XL | Optimum Extra | Ice Blue | N70129 |

Table 6. Stock trial lenses, basic UDI-DI 731686scleralTrialOEMTSQD.

| Design | Material | Colour | BC | Dia | Power | Art No |
|------------|---------------|----------|--------|------|-------|--------|
| Rose K2 XL | Optimum Extra | Ice Blue | 6,0 | 14,6 | 18,0 | N70291 |
| | | | 6,2 | 14,6 | 15,0 | N70292 |
| | | | 6,4 | 14,6 | 12,0 | N70293 |
| | | | 6,5 | 14,6 | 11,0 | N70294 |
| | | | 6,6 | 14,6 | 10,0 | N70295 |
| | | | 6,7 | 14,6 | -9,0 | N70296 |
| | | | 6,8 | 14,6 | -8,0 | N70297 |
| | | | 6,9 | 14,6 | -7,0 | N70298 |
| | | | 7,0 | 14,6 | -6,0 | N70299 |
| | | | 7,1 | 14,6 | -5,0 | N70300 |
| | | | 7,2 | 14,6 | -4,0 | N70301 |
| | | | 7,3 | 14,6 | -3,0 | N70302 |
| | | | 7,4 | 14,6 | -2,0 | N70303 |
| | | | 7,6 | 14,6 | -1,0 | N70304 |
| | | | 7,8 | 14,6 | 0,0 | N70305 |
| 8,0 | 14,6 | +1,0 | N70306 | | | |









REC-1140 DoC Rigid Trial Lenses 260611

Final Audit Report

2026-06-11

| | |
|-----------------|--|
| Created: | 2026-06-11 |
| By: | David Lingmark (david.lingmark@multilens.se) |
| Status: | Signed |
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