

ID: REC-1140  
Title: Declaration of Conformity Rigid Trial Lenses  
Date: 2026-02-16

**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).

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

Place and Date: Mölnlycke, 2026-02-16

Signature: *Marie Leander*  
Marie Leander (Feb 16, 2026 12:53:38 GMT+1)

Name and Function: Marie Leander, PRRC

Place and Date: Mölnlycke, 2026-02-16

Signature: *Fredrik Pamp*  
Fredrik Pamp (Feb 16, 2026 13:23:21 GMT+1)

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  
Basic UDI-DI: 731686cornealTrialOEVQ

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

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 731686cornealTrialOEVQ.

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			

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Design	Material	Colour	BC	Dia	Power	Art No
			5,5	8,3	19,0	N70233
			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

Design	Material	Colour	BC	Dia	Power	Art No
			7,3	11,2	-7,0	N70281
			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  
 Basic UDI-DI: 731686cornealTrialBES4W

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 731686cornealTrialBES4W.

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	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

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			7,8	9,6	+3,0	N70332
			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

Basic UDI-DI: 731686scleralTrialOEXY

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 731686scleralTrialOEXY.

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 260216

Final Audit Report

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