

ID: REC-0959
Title: Declaration of Conformity Rigid Contact Lenses
Date: 2025-11-11

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 Contact Lenses (listed in detailed in appendix)		
Product Classification:	Class IIa		
Single Registration Number (Eudamed):	SE-MF 000002792		
Common Specifications applied:	Not applicable		
Notified Body, Notified Body number	BSI Group The Netherlands B.V., 2797		
Conformity assessment procedure:	Annex IX MDR (EU) 2017/745		
Certificate number	MDR 763785		
Basic UDI-DI:	Product	Material	Basic UDI-DI
	Corneal rigid gas permeable contact lens	Boston ES	731686cornealBESDH
		Boston XO	731686cornealBXOF2
		Optimum Extra	731686cornealOEAT
		Optimum Infinite	731686cornealOIB3
	Scleral and corneo scleral rigid gas permeable contact lens	Boston XO	731686scleralBXOHU
		Optimum Extra	731686scleralOECT
		Optimum Infinite	731686scleralOID3
Intended purpose:			
Corneal contact lenses: Reusable corneal contact lens intended for daily wear in order to improve visual acuity by correction of myopia, hyperopia, presbyopia, and/or astigmatism.			
Scleral and corneo-scleral contact lens: Reusable scleral and corneo-scleral contact lens intended for daily wear in order to improve visual acuity by correction of myopia, hyperopia, presbyopia, and/or astigmatism.			

Place and Date: Mölnlycke,
11/11/2025

Signature:

Marie Leander
Marie Leander (Nov 11, 2025 10:43:15 GMT+1)

Name and
Function

Marie Leander, PRRC

Place and Date: Mölnlycke,
11/11/2025

Signature:

Fredrik Pamp
Fredrik Pamp (Nov 11, 2025 15:38:30 GMT+1)

Name and
Function

Fredrik Pamp, CEO

Signed on behalf of Multilens AB

Appendix to Declaration of Conformity

Corneal RGP lenses, Boston ES
Basic UDI-DI: 731686cornealBESDH

Table 1. List of Corneal rigid gas permeable (RGP) contact lenses with Boston ES

Design	Material	Color	Art No
A Design	Boston ES	Blue	N30504
		Clear	N30509
		Green	N30506
		Grey	N30505
Envision	Boston ES	Blue	N30520
		Clear	N30525
		Green	N30522
		Grey	N30521
P1	Boston ES	Blue	N30536
		Clear	N30541
		Green	N30538
		Grey	N30537
P1 KE	Boston ES	Clear	N30557
		Green	N30554
		Grey	N30553
		Blue	N30552
P2	Boston ES	Blue	N30568
		Clear	N30573
		Green	N30570
		Grey	N30569
P2 KE	Boston ES	Blue	N30584
		Clear	N30589
		Green	N30586
		Grey	N30585
P3	Boston ES	Blue	N30600
		Clear	N30605
		Green	N30602
		Grey	N30601
P3 KE	Boston ES	Blue	N30616
		Clear	N30621
		Green	N30618
		Grey	N30617
ML RGP Individual	Boston ES	Blue	N30628
		Clear	N30633
		Green	N30631
		Grey	N30630
Rose K2 IC	Boston ES	Blue	N30220
		Clear	N30225
		Green	N30222

ID: REC-0959
Date: 2025-11-11

Design	Material	Color	Art No
		Grey	N30221
Rose K2 KC	Boston ES	Blue	N30204
		Clear	N30209
		Green	N30206
		Grey	N30205
Rose K2 NC	Boston ES	Blue	N30244
		Clear	N30249
		Green	N30246
		Grey	N30245
Rose K2 PG	Boston ES	Blue	N30230
		Clear	N30235
		Green	N30232
		Grey	N30231

Corneal RGP lenses, Boston XO
Basic UDI-DI: 731686cornealBXOF2

Table 2. List of Corneal rigid gas permeable (RGP) contact lenses with Boston XO

Design	Material	Color	Art No
A Design	Boston XO	Blue	N30510
		Green	N30511
		Ice Blue	N30512
Envision	Boston XO	Blue	N30526
		Green	N30527
		Clear	N30528
P1	Boston XO	Blue	N30542
		Green	N30543
		Ice Blue	N30544
P1 KE	Boston XO	Blue	N30558
		Green	N30559
		Ice Blue	N30560
P2	Boston XO	Blue	N30574
		Green	N30575
		Ice Blue	N30576
P2 KE	Boston XO	Blue	N30590
		Green	N30591
		Ice Blue	N30592
P3	Boston XO	Blue	N30606
		Green	N30607
		Ice Blue	N30608
P3 KE	Boston XO	Blue	N30622
		Green	N30623
		Ice Blue	N30624
ML RGP Individual	Boston XO	Blue	N30638

ID: REC-0959
Date: 2025-11-11

		Ice Blue	N30639
		Green	N30640
Rose K2 IC	Boston XO	Blue	N30226
		Ice Blue	N30228
		Green	N30227
Rose K2 KC	Boston XO	Blue	N30210
		Ice Blue	N30212
		Green	N30211
Rose K2 NC	Boston XO	Blue	N30250
		Ice Blue	N30252
		Green	N30251
Rose K2 PG	Boston XO	Blue	N30236
		Ice Blue	N30238
		Green	N30237

Corneal RGP lenses, Optimum Extra
Basic UDI-DI: 731686cornealOEAT

Table 3. List of Corneal rigid gas permeable (RGP) contact lenses with Optimum Extra

Design	Material	Color	Art No
A Design	Optimum Extra	Blue	N30810
		Clear	N30294
		Green	N30808
		Ice blue	N30295
Envision	Optimum Extra	Blue	N30812
		Clear	N30296
		Green	N30813
		Ice blue	N30297
ML RGP Individual	Optimum Extra	Blue	N30811
		Clear	N30298
		Green	N30809
		Ice Blue	N30299
Rose K2 IC	Optimum Extra	Blue	N30732
		Clear	N30717
		Green	N30728
		Ice blue	N30712
Rose K2 KC	Optimum Extra	Blue	N30730
		Clear	N30715
		Green	N30726
		Ice blue	N30710
Rose K2 NC	Optimum Extra	Blue	N30731
		Clear	N30716
		Green	N30727
		Ice blue	N30711
Rose K2 PG	Optimum Extra	Blue	N30733
		Clear	N30718
		Green	N30729
		Ice blue	N30713

Corneal RGP lenses, Optimum Infinite
Basic UDI-DI: 731686cornealOIB3

Table 4. List of Corneal rigid gas permeable (RGP) contact lenses with Optimum Infinite

Design	Material	Color	Art No
Rose K2 IC	Optimum Infinite	Blue	N30723
Rose K2 KC	Optimum Infinite	Blue	N30721
Rose K2 NC	Optimum Infinite	Blue	N30722
Rose K2 PG	Optimum Infinite	Blue	N30724

ID: REC-0959
Date: 2025-11-11

Scleral and corneo-scleral RGP lenses, Boston XO
Basic UDI-DI: 731686scleralIBXOHU

Table 5. List of scleral and corneo scleral rigid gas permeable (RGP) contact lens with Boston XO

Design	Type	Material	Color	Art No
Onefit std	Standard	Boston XO	Clear	N20431
	Prism ballast			N30954
	SC standard			N30904
	SC prism ballast			N30928
	SC Quad			N30922
	SC Symtoric			N30916
	SC TPC			N30910
	Symtoric			N20441
	TPC			N20460
	Quad			N30753
	Standard		Ice blue	N20420
	Prism ballast			N30955
	SC standard			N30905
	SC prism ballast			N30929
	SC Quad			N30923
	SC Symtoric			N30917
	SC TPC			N30911
	Symtoric			N20442
	TPC			N20461
	Quad			N30752
Onefit MF	TPC	Boston XO	Clear	N20466
			Ice blue	N20467
Onefit MED	Standard	Boston XO	Clear	N20615
	Quad			N20481
	TPC			N20624
	Standard		Ice blue	N20614
	Quad			N20480
	TPC			N20625
Rose K2 XL	Standard	Boston XO	Clear	N30259
			Ice blue	N30258

Scleral and corneo-scleral RGP lenses, Optimum Extra
Basic UDI-DI: 731686scleralOECT

Table 6. List of scleral and corneo scleral rigid gas permeable (RGP) contact lens with Optimum Extra

Design	Type	Material	Color	Art No
Onefit std	Standard	Optimum Extra	Clear	N30462
	Prism ballast			N30950
	Quad			N30757
	Symtoric			N20446
	TPC			N20464
	SC			N30900
	SC Prism ballast			N30924
	SC Quad			N30918
	SC Symtoric			N30912
	SC TPC			N30906
	Standard		Ice blue	N30463
	Prism ballast			N30951
	Quad			N30756
	Symtoric			N20445
	TPC			N20465
	SC			N30901
	SC Prism ballast			N30925
	SC Quad			N30919
	SC Symtoric			N30913
	SC TPC			N30907
Onefit MF	Standard	Optimum Extra	Clear	N30466
	TPC			N20470
	Standard		Ice blue	N30467
	TPC			N20471
Onefit MED	Standard	Optimum Extra	Clear	N20613
	Quad			N20479
	TPC			N20628
	Standard		Ice blue	N20612
	Quad			N20478
	TPC			N20629
Onefit MED MF	Standard	Optimum Extra	Clear	N20619
	Standard		Ice blue	N20618
Onefit MED+	Standard	Optimum Extra	Clear	N30685
	Quad			N30687
	TPC			N30686
	Standard		Ice blue	N30682
	Quad			N30684
	TPC			N30683
Onefit MED+ MF	Standard	Optimum Extra	Clear	N30699
			Ice blue	N30698
Rose K2 XL	Standard	Optimum Extra	Clear	N30719

Design	Type	Material	Color	Art No
			Ice blue	N30714

Scleral and corneo-scleral RGP lenses, Optimum Infinite
Basic UDI-DI: 731686scleralOID3

Table 7. List of scleral and corneo scleral rigid gas permeable (RGP) contact lenses with Optimum Infinite

Design	Type	Material	Color	Art No
Onefit	Standard	Optimum Infinite	Clear	N20640
	Prism ballast			N30952
	Quad			N30759
	Symtoric			N20642
	TPC			N20641
	SC			N30902
	SC Prism ballast			N30926
	SC Quad			N30920
	SC Symtoric			N30914
	SC TPC			N30908
	Standard		Ice blue	N20630
	Prism ballast			N30953
	Quad			N30758
	Symtoric			N20633
	TPC			N20631
	SC			N30903
	SC Prism ballast			N30927
	SC Quad			N30921
	SC TPC			N30909
Onefit MF	Standard	Optimum Infinite	Clear	N20644
	TPC			N20645
	Standard		Ice Blue	N20634
	TPC			N20635
Onefit MED	Standard	Optimum Infinite	Clear	N20647
	Quad			N20485
	TPC			N20648
	Standard		Ice blue	N20637
	Quad			N20484
	TPC			N20638
Onefit MED MF	Standard	Optimum Infinite	Clear	N20649
			Ice blue	N20639
Onefit MED+	Standard	Optimum Infinite	Clear	N30691
	Quad			N30693
	TPC			N30692
	Standard		Ice blue	N30688
	Quad			N30690
	TPC			N30689

ID: REC-0959
Date: 2025-11-11



Design	Type	Material	Color	Art No
Onefit MED+ MF	Standard	Optimum Infinite	Clear	N30751
			Ice blue	N30750
Rose K2 XL	Standard	Optimum Infinite	Clear	N30734
			Ice blue	N30725

REC-0959 DoC Rigid Contact Lenses 251111

Final Audit Report

2025-11-11

Created:	2025-11-11
By:	Marie Meyer (Marie.meyer@multilens.se)
Status:	Signed
Transaction ID:	CBJCHBCAABAAXTITC2msdZSiZKueMIPnmpQSGU4TKbKn

"REC-0959 DoC Rigid Contact Lenses 251111" History

-  Document created by Marie Meyer (Marie.meyer@multilens.se)
2025-11-11 - 9:25:20 AM GMT
-  Document emailed to Marie Leander (marie.leander@multilens.se) for signature
2025-11-11 - 9:25:25 AM GMT
-  Email viewed by Marie Leander (marie.leander@multilens.se)
2025-11-11 - 9:33:15 AM GMT
-  Document e-signed by Marie Leander (marie.leander@multilens.se)
Signature Date: 2025-11-11 - 9:43:15 AM GMT - Time Source: server
-  Document emailed to Fredrik Pamp (fredrik.pamp@multilens.se) for signature
2025-11-11 - 9:43:17 AM GMT
-  Email viewed by Fredrik Pamp (fredrik.pamp@multilens.se)
2025-11-11 - 2:38:15 PM GMT
-  Document e-signed by Fredrik Pamp (fredrik.pamp@multilens.se)
Signature Date: 2025-11-11 - 2:38:30 PM GMT - Time Source: server
-  Agreement completed.
2025-11-11 - 2:38:30 PM GMT