

ID: REC-0958
Title: Declaration of Conformity Soft Contact Lenses
Date: 2025-10-20



Declaration of Conformity

Multilens AB, Skinnefjällsv. 1 43540 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:	Soft Contact Lenses (listed in detail 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:	Material	Basic UDI-DI
	ML65	731686softML65B9
	ML75	731686softML75BC
	Si-H	731686softSiHYL
	GM Advance 49	731686softGM49A6
Intended purpose: Reusable soft 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, 2025-10-20

Place and Date: Mölnlycke, 2025-10-20

Signature:

Marie Leander
Marie Leander (Oct 20, 2025 10:05:08 GMT+2)

Signature:

Fredrik Pamp
Fredrik Pamp (Oct 20, 2025 14:23:22 GMT+2)

Name and
Function

Marie Leander, PRRC

Name and
Function

Fredrik Pamp, CEO

Signed on behalf of Multilens AB

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Appendix to Declaration of Conformity

Design	Material (colour)	Art No
Soft std	ML 65 (clear)	N50023
	ML 75 (clear)	N50060 / N70345
	Si-H (clear)	N50026 / N70339 / N70340 N70341
	Si-H (blue)	N50027 / N70342 / N70343 N70344
Soft Child	ML 65 (clear)	N50047
	ML 75 (clear)	N50062
	Si-H (clear)	N50050
	Si-H (blue)	N50051
Soft DCT	ML 65 (clear)	N50035
	ML 75 (clear)	N50065
	Si-H (clear)	N50038
	Si-H (blue)	N50039
Soft KKL	ML 65 (clear)	N50029 / N50055
	ML 75 (clear)	N50064 / N50071 / N70335 N70336 / N70337 / N70338
	Si-H (clear)	N50032 N50057
	Si-H (blue)	N50033 N50058
Soft Thin	ML 65 (clear)	N50041
	ML 75 (clear)	N50061
	Si-H (clear)	N50044
	Si-H (blue)	N50045
Soft Individual	ML 65 (clear)	N50072
	ML 75 (clear)	N50073
	Si-H (clear)	N50075
	Si-H (blue)	N50076
Soft PostSurg	ML 75 (clear)	N50066
Rose K2 Soft	ML 75 (clear)	N30720
	GM Advance 49 (clear)	N30276
	GM Advance 49 (blue)	N30277 / N70115 / N70116 N70117 / N70118 / N70119 N70120 / N70121 / N70122

Declaration of Conformity Soft Contact Lenses 251020

Final Audit Report

2025-10-20

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