



EC DECLARATION OF CONFORMITY



We, *Cantor and Nissel Ltd, Market Place, Brackley, Northamptonshire, NN13 7NN*

European Representative: **Emergo Europe, Prinsessegracht 20 4514 AP, The Hague, THE NETHERLANDS**

Hereby declare under our sole responsibility that the CE marked product(s) to which this declaration relates,

Non-Sterile RGP Lenses

- Apex
- Aqualine MF
- MetrO₂
- Nissel Keratoconus II Rigid
- Nissel Sixteen-50
- Nissel Eighteen-20
- 4F
- Oxyflex (Paraperm, Fluroperm, Boston)
- McGuire
- Keratoconus
- Tricurve
- Custom Design – Practitioner defined parameters

Have been classified as Class IIa, according to Annex IX, rule 5,

and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices amended by Directive 2007/47/EC

and are in conformity either partly, fully with the relevant standards below:

BS EN ISO 10012:2003	BS EN ISO 10993-1:2020	BS EN ISO 11978:2017+A1:2020	BS EN ISO 11987:2012
BS EN ISO 13485:2016	BS EN ISO 14155:2020	BS EN ISO 14534:2015	BS EN ISO 14971:2019
BS EN ISO 15223-1:2016	BS EN ISO 14644-1:2015	BS EN ISO 18369-1:2017	BS EN ISO 18369-2:2017
BS EN ISO 18369-3:2017			

and are subject to the procedure set out in Annex V of the Council Directive 93/42/EEC amended by Directive 2007/47/EC

Sterile Soft Lenses

- Cantor Cosmetic[^]
- Cantor Prosthetic[^]
- ChromaGenTM [^]
- Hydrocyl (Pastel Tints) (38, 60, 67, 77, SiH, GMA, Zero 6T[®])
- Hydrofit (Pastel Tints) (38, 60, 67, 77, SiH, GMA, Zero 6[®])
- Hydrolens (Pastel Tints) (38, 60, 67, 77, SiH, GMA)
- Meridian Toric
- 30 Days[^]
- Nissel 55
- Nissel Custom[^]
- Nissel Keratoconus II Soft
- OmniFlex[^]
- PV 150, 200, 250
- Thames
- X-Chrom[^]
- SiHlk[^]

[^]Includes Toric Variation

Have been classified as Class IIa, according to Annex IX, rule 5,



EC DECLARATION OF CONFORMITY



and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices amended by Directive 2007/47/EC

and are in conformity either partly, fully with the relevant standards below:

BS EN 556-1:2001	BS EN ISO 10012:2003	BS EN ISO 10993-1:2020	BS EN ISO 11978:2017
BS EN ISO 11987:2012	BS EN ISO 13485:2016	BS EN ISO 14534:2015	BS EN ISO 14644-4:2001
BS EN ISO 14971:2019	BS EN ISO 15223-1:2016	BS EN ISO 14644-2:2015	BS EN ISO 11737-1:2018
BS EN ISO 11737-2:2020	BS EN ISO 14644-1:2015	BS EN ISO 17665-1:2006	
BS EN ISO 14644-5:2004	BS EN ISO 14644-6:2007	BS EN ISO 18369-1:2017	
BS EN ISO 18369-3:2017	BS EN ISO 14155:2020	BS EN ISO 18369-2:2017	

and are subject to the procedure set out in Annex V of the Council Directive 93/42/EEC amended by Directive 2007/47/EC

This declaration is made on base of the quality assurance certificate N°. GB19/964582 delivered by Notified Body n° 1639

SGS Belgium NV
SGS House
Noorderlaan 87
2030 Antwerpen
Belgium

This certificate is valid only for devices released from the following site:

Cantor and Nissel Ltd
Market Place
Brackley
Northamptonshire
NN13 7NN
United Kingdom

Signature:

Date:

17 February 2021

Name:

Garth Barnard

Position:

Managing Director