

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

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

Non-Sterile RGP lenses

Apex Rigid Lenses
Aqualine MF Series
Bifocal RGP Lenses
Cantor Hybrid (Formerly EyeBrid)
Cantor Hybrid Cone (Formerly EyeBrid Cone)
MetrO₂
Nissel KII Rigid
Nissel Sixteen-50
4F
Oxyflex / Percon
Toric Rigid Lenses
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 10993-1:2009	BS EN ISO 11978:2014	BS EN ISO 11987:2012
ISO 13485:2003	BS EN ISO 14155:2011	BS EN ISO 14534:2015	BS EN ISO 14971:2012
BS EN ISO 15223-1:2012	BS EN ISO 19011:2011	BS EN ISO 11737-1:2006	BS EN ISO 14644-1:1999
BS EN ISO 14644-2:2000	ISO 18369-1:2009	BS EN ISO 18369-2:2012	BS EN ISO 18369-3:2006

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

Bandage Lenses	Nissel Custom Hand Painted Lenses
Cantor Cosmetics	Nissel KII Soft
Cantor Prosthetics	Nissel Naturals
ChromaGen™	Pastel Tints
Hydrocyl Soft Toric	PV Series Multifocal Soft Lenses
Hydrofit	Thames Design
Hydrolens	X-Chrom
Meridian Toric	

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EC DECLARATION OF CONFORMITY



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 10993-1:2009	BS EN ISO 11978:2014
BS EN ISO 11987:2012	ISO 13485:2003	BS EN ISO 14155:2011	BS EN ISO 14534:2015
BS EN ISO 14971:2012	BS EN ISO 15223-1:2012	BS EN ISO 19011:2011	BS EN ISO 11737-1:2006
ISO 11737-2:2009	BS EN ISO 14644-1:1999	BS EN ISO 14644-2:2000	BS EN ISO 14644-4:2001
BS EN ISO 14644-5:2004	BS EN ISO 14644-6:2007	BS EN ISO 17655-1:2006	ISO 18369-1:2009
BS EN ISO 18369-2:2012	BS EN ISO 18369-3:2006		

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°. GB96/7963 delivered by Notified Body n° 0120

SGS United Kingdom Ltd,
Unit 202B
Worle Parkway
Weston Super Mare
BS22 6WA
United Kingdom

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:

A handwritten signature in blue ink, appearing to be 'DC' followed by a stylized flourish.

Name: David Cantor

Date: 15th September 2015

Position: Managing Director