EU Quality Management System Certificate GB23/00000065

The management system of

Cantor & Nissel Limited

Market Place Brackley Northamptonshire NN13 7NN United Kingdom
SRN: GB-MF000009886

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products
Class IIa Devices:
MDN1206
506072089RgpLensJQ (B-UDI) RGP Lenses
506072089SoftLensJC (B-UDI) Soft Sterile Contact Lenses

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on - GB/PC/05038 - CTC 1.5

Authorized representative name and address (if relevant): Emergo Europe ; Westervoortsedijk 60 6827 AT, Arnhem, NL ;
Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 18 May 2023 until 10 February 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 August 2027
Issue 2. Certified since 10 February 2023

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
SGS Belgium NV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com