Declaration of conformity

AUROLAB
No.1, Sivagangai Main Road
Veerapanjan
Madurai- 625 020 India.
TEL: +91-94892 12354/+91-73395 71000
E-MAIL- info@aurolab.com
WEB: www.aurolab.com

Digitally signed by Pereteatco Alina
Date: 2023.08.04 21:14:31 EEST
Reason: MoldSign Signature
Location: Moldova

We declare that under our sole responsibility that
MD Code: 0105 **MDS Code: 7006-1**
Product: INTRAOCULAR LENS **Brand Name: Aurolens**
GMDN Code- Anterior Chamber Intraocular Lens, Pseudophakic – "35655"
UMDNS Code- Anterior Chamber Intraocular Lens, Pseudophakic- 16068
Models: Single Piece lenses: A5520, A5520R, A5525, A5525R, A5528, A5528R, A5530, A5530R, A5527R, A6028R
GMDN Code- Posterior Chamber Intraocular Lens, Pseudophakic – "35658"
UMDNS Code- Posterior Chamber Intraocular Lens, Pseudophakic – 16071
Models: Single Piece Lenses: S3500, S3500L, S3525L, S3550, S3550EL, S3550L, S3600L, S3602, S3602L, S3642, S3652, S3P500, S3P550L, S3P602, SC6530, SN3550EL, SN3600L, SM3600, SM3600L, SM3650, SN3650,S3525, S3602EL, SN3600, S3600,S3500R,S3550R,S3600R,S3602R, IF6030*,IF3602L*
Three piece lenses:
B1602, B3602
Lot Nos:

_____

_____

_____

Sterilization Batch No: _____
For all batch numbers / serial numbers which are manufactured according to the specification of the Technical Documentation Issue 21 and issue date: 20.11.2021documented in the general batch survey
Of class II b Rule No. 8 according to Annex IX of MDD 93/42/EEC
Meets all the provisions of the directive 93/42/EEC which apply to it.
Applied Standards: **REFER LIST OF HARMONIZED STANDARDS IN TECHNICAL FILE**
Technical documentation Issue 21 and issue date: 20.11.2021
Applied conformity assessment procedure **Annex II without requirement of Annex II.4 of MDD 93/42/EEC**

Notified Body:
TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nüernberg, Germany
Notified body number: 0197

European representative:
mdi Europa GmbH
Langenhagener Straße 71
D-30855 Langenhagen, Germany
Reg No: HD 2067790-1

Place / Date: Madurai / _____

Signature

Form Approval:

QA Manager

Form No: QA – 16A QAP- 24 Issue No: 31 Issue Date: 20.11.2021 Effective Date: 27.11.2021

Issued By: _____
QA Manager

Approved By: _____
Senior RA Manager

*Non CE Model