CERTIFICATE

This is to certify that the company

MORIA S.A.

15, rue Georges Besse
92160 Antony
France

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design and development, manufacture, distribution and servicing of Applanator leses, Artificial Chambers, Blades for trephines, Calipers, Cannula, Curettes, Forceps, Graduated rings, Hooks, Iris Retractors, Keratomes, Knives, Lacrimal pathway irrigation cannulas, Lid Plates, Lids retractors, Loops, Markers, Microkeratomes - Blades,- Console adapter,- Control unit,- Cords,- Footswitches,- Handpieces,- Heads,- Rings,- Sterile sets,- Tubings, Microsurgical instrument, Needle, Needle holders, Probes and dilators, Punch, Pupil dilator, Retractors, Ring, Ring for Artificial Chambers, Scalpels, Scissors, Scleral depressors, Spatula, Speculums, Sterile sets, Sterilization and storage boxes, Tonometers, Trephine, Tubing for artificial chambers, Tubings, as used in ophthalmology.
- AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	542253 MDSAP16
Certificate unique ID	170774061
Effective date	2021-01-28
Expiry date	2022-11-12
Frankfurt am Main	2021-01-28

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
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Product Manager

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Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de
DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.
Visit https://www.mydqs.com/en/customers/customer-database.html to validate this certificate.

413.01 Version 6.0

Annex to certificate
Certificate registration No.: 542253 MDSAP16
Certificate unique ID: 170774061
Effective date: 2021-01-28

MORIA S.A.

15, rue Georges Besse
92160 Antony
France

Audited site	DUNS No., site scope and country-specific requirements
MORIA S.A. 15, rue Georges Besse 92160 Antony France	Design and development of Applanator leses, Artificial Chambers, Blades for trephines, Calipers, Cannula, Curettes, Forceps, Graduated rings, Hooks, Iris Retractors, Keratomes, Knives, Lacrimal pathway irrigation cannulas, Lid Plates, Lids retractors, Loops, Markers, Microkeratomes - Blades,- Console adapter,- Control unit,- Cords,- Footswitches,- Handpieces,- Heads,- Rings,- Sterile sets,- Tubings, Microsurgical instrument, Needle, Needle holders, Probes and dilators, Punch, Pupil dilator, Retractors, Ring, Ring for Artificial Chambers, Scalpels, Scissors, Scleral depressors, Spatula, Speculums, Sterile sets, Sterilization and storage boxes, Tonometers, Trephine, Tubing for artificial chambers, Tubings. **- AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **DUNS No.: 275937506**
MORIA S.A. 27, rue du pied de Fourche 03160 Bourbon l'Archambault France	Manufacture and servicing of Applanator leses, Artificial Chambers, Blades for trephines, Calipers, Cannula, Curettes, Forceps, Graduated rings, Hooks, Iris Retractors, Keratomes, Knives, Lacrimal pathway irrigation cannulas, Lid Plates, Lids retractors, Loops, Markers, Microkeratomes - Blades,- Console adapter,- Control unit,- Cords,- Footswitches,- Handpieces,- Heads,- Rings,- Sterile sets,- Tubings, Microsurgical instrument, Needle, Needle holders, Probes and dilators, Punch, Pupil dilator, Retractors, Ring, Ring for Artificial Chambers, Scalpels, Scissors, Scleral depressors, Spatula, Speculums, Sterile sets, Sterilization and storage boxes, Tonometers, Trephine, Tubing for artificial chambers, Tubings **- AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **DUNS No.: 395035603**

Annex to certificate
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92160 Antony
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Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821