



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



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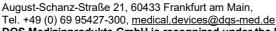
DQS Medizinprodukte GmbH

W leuc

Sigrid Uhlemann

Managing Director

Szymon Kurdyn **Product Manager**







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

MORIA S.A.

15, rue Georges Besse 92160 Antony France

DUNS No., site scope and country-specific requirements

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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MORIA S.A.

15, rue Georges Besse 92160 Antony France

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

