EU DECLARATION OF CONFORMITY (DoC) TO MEDICAL DEVICE REGULATIONS

We, **CRISTALENS INDUSTRIE, 4 rue Louis Broglie, 22300 LANNION, France**, declare under our sole responsibility that the products below including all derived products designed and manufactured under CRISTALENS INDUSTRIE to which this declaration relates are in conformity with the following standard(s) or other normative document(s):

Reference to Harmonized Standards:

- *Council Directive 93/42/EEC and Council Directive 2007/47/EC on Medical Devices (MDD)*
- *(France) Livre II : Dispositifs médicaux, dispositifs médicaux de diagnostic in vitro et autres produits et objets réglementés dans l'intérêt de la santé publique – Titre 1er : Dispositifs médicaux*
- *NF EN ISO 13485:2016 - Quality system requirements for regulatory purposes*
- *NF EN ISO 14971:2013 - Application of risk management to medical devices*
- *NF EN 62366-1:2015 - Application of usability engineering to medical devices*
- *NF EN ISO 15223-1:2017 - Symbols to be used with medical device labels, labelling and information to be supplied*
- *NF EN ISO 10993-1 up to 13 - Biological evaluation of medical devices*
- *NF EN ISO 10993-16 up to 19 - Biological evaluation of medical devices*
- *MEDDEV 2.7/1 Rev. 4, Clinical evaluations*
- *NF EN ISO 11607-1:2018 - Packaging for terminally sterilized medical devices - Requirements for materials, sterile barrier systems and packaging systems*
- *NF EN ISO 11607-2:2018 - Packaging for terminally sterilized medical devices - Validation requirements for forming, sealing and assembly processes*
- *NF EN 556-1:2002 - Sterilization of medical devices - Requirements terminally sterilized medical devices*
- *NF EN ISO 11737-1:2006 - Sterilization of medical devices - Determination of a population of microorganisms on products*
- *NF EN 1041+A1:2013 - Information supplied by the manufacturer with medical devices*
- *MEDDEV 2.12/2 Rev.2, Guidelines on post-market clinical follow-up (PMCF) studies*
- *MEDDEV 2.12/1 Rev.8, Medical devices vigilance systems*

Reference to Common Technical Specifications (CTS):

- *NF EN ISO 11979-8:2017 - Ophthalmic implants - Fundamental requirements*
- *NF EN ISO 11979-2:2014 - Ophthalmic implants - Optical properties and test methods*
- *NF EN ISO 11979-3:2013 - Ophthalmic implants - Mechanical properties and test methods*
- *NF EN ISO 11979-4+A1:2009 - Ophthalmic implants - Labelling and information*
- *NF EN ISO 11979-5:2006 - Ophthalmic implants - Biocompatibility*
- *NF EN ISO 11979-6:2014 - Ophthalmic implants - Shelf life and transport stability*
- *NF EN ISO 11979-9 and A1:2014 - Ophthalmic implants - Multifocal intraocular lenses*
- *NF EN ISO 14644-1:2016 - Cleanrooms and associated controlled environments*

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Date: 2021.10.08 12:07:57 EEST
Reason: MoldSign Signature
Location: Moldova

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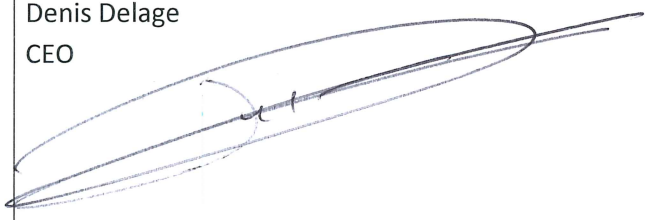
List of medical devices (as defined per Art.1 of Dir.93/42/EEC) concerned by the DoC:

Device(s) category	*Product name*	*Diopter range*			*Risk classification (per Ax IX of Dir.93/42/EEC)*	*Notified Body name and number*	*Conformity assessment procedure and Certificate number*
Sterile preloaded hydrophobic intraocular lenses	ARTIS PL *E*	From 0D to +36D by 0.5D			IIb (Rule 8, Annex IX of Directive 93/42/EEC concerning medical devices)	GMED (0459)	Full Quality Assurance System, Annex II - excluding section 4 Directive 93/42/EEC concerning medical devices (certificate n°8275) ISO 13485:2016 – NF EN ISO 13485:2016 certification of the Quality Management System (certificate n°20709)
	ARTIS Y PL	From 0D to +36D by 0.5D					
	ARTIS V15 PL	From 0D to +36D by 0.5D					
	ARTIS T PL *E* *(Toric)*	Cylinder		Power			
		From + 0.75D to + 6.00D by 0.75D		From +9D to +36D by 0.5D			
	ARTIS PL M *(Multifocal)*	Addition		Power			
		From +2.00D to +3.50D by 0.25D		From +9D to +36D by 0.5D			
	ARTIS SYMBIOSE *(Toric multifocal)*	Addition profiles	Cylinder	Power			
		Mid Plus	From 0.00D to +3.75D by 0.25D	From +9D to +36D by 0.5D			
	EAZ	From 0D to +36D by 0.5D					
	EAZ-Y	From 0D to +36D by 0.5D					
	NAVIGO	From 0D to +36D by 0.5D					
	EOS mp4	From 0D to +36D by 0.5D					
Sterile hydrophilic intraocular lenses	LUCIS	From -10D to +31D by 0.5D					
	CLARE	From +9D to +31D by 0.5D					
	CRISTAL	From +9D to +31D by 0.5D					
	REVERSO Monofocal	From -6D to +6D by 0.5D					
	REVERSO Multifocal	Addition		Power			
		From +1.50D to +3.50D by 0.5D		From -3D to +3D by 0.5D			
	ASK	From +9D to +31D by 0.5D					
	QUATUOREVO	From +9D to +31D by 0.5D					

This declaration is also based on the technical documentations MASTER FILE_IOL_FOB_MONO, MASTER FILE_IOL_FOB_MULTI, MASTER FILE_IOL_FIL_MONO and MASTER FILE_IOL_FIL_ADD-ON.

October 9th, 2019
Lannion, France,
Denis Delage
CEO



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The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.
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