

URGENT: SAFETY NOTICE (FSN) - DEVICE RECALL

Medical devices concerned: Hydrophilic acrylic intraocular lenses CLARE, QUATUOREVO, CRISTAL, LUCIS
Preloaded hydrophobic acrylic intraocular lenses ARTIS Y PL, ARTIS PL E

Dear Cristalens Industrie Customer,

We hereby inform you that we are carrying out a batch recall as a precautionary measure.

Cristalens Industrie has been informed of 2 cases of intraocular lenses with unexpected refractive errors.

As a precaution, Cristalens Industrie is recalling the batches potentially involved.

Users of batches concerned by the recall have already been informed.

Hazard description: Risk of unsatisfactory post-operative refractive results.

In appendix 1, you will find the references of the intraocular lenses concerned by this notice.

Please follow the instructions below:

- 1- Cristalens has identified that affected devices have been provided to your establishment. Check your stock management systems and your customers' warehouses: Please do not use intraocular lenses with the serial numbers shown in Appendix 1. Please return intraocular lenses with the serial numbers shown in Appendix 1. Please provide us with the references of the intraocular lenses with the serial numbers shown in Appendix 1 that have been fitted and the date of implantation.
- 2- Immediately transmit this notice to all persons who should be informed of this notice in your establishment, and/or to any other establishment where the affected products have been transferred.
- 3- Return the duly completed, stamped and signed reply form below without delay to the following address:
materiovigilance@cristalens.fr
- 4- Contact your usual customer service department at export.ci@cristalens.fr if you have any questions.
- 5- Any correspondence or discussions relating to this notice must mention the following reference:
FSN_RC_00641

We inform you that this notice has been communicated to the competent national authorities.

Committed to providing you and your customers with the highest quality products, Cristalens Industrie thanks you for your cooperation and is fully aware of the inconvenience caused.

If you have any questions concerning this information, please contact Cristalens Industrie :
By telephone at + 33 2 96 48 92 92, or by e-mail at materiovigilance@cristalens.fr

Yours sincerely
Mr Denis DELAGE
Chairman

Appendix 1: List of medical devices concerned by this safety notice
Appendix 2: Response form must be completed, stamped and signed.

Appendix 1: List of medical devices concerned by this safety notice - reference: FSN_RC_00641
Hydrophilic acrylic intraocular lens model CLARE and model QUATUOREVO

Page1

CLARE 11.0D - Batch 2315297

2315297002	2315297014	2315297026	2315297038	2315297050	2315297076
2315297003	2315297015	2315297027	2315297039	2315297051	2315297078
2315297004	2315297016	2315297028	2315297040	2315297052	2315297080
2315297005	2315297017	2315297029	2315297041	2315297053	2315297082
2315297006	2315297018	2315297030	2315297042	2315297055	2315297083
2315297007	2315297019	2315297031	2315297043	2315297056	2315297085
2315297008	2315297020	2315297032	2315297044	2315297057	
2315297009	2315297021	2315297033	2315297045	2315297058	
2315297010	2315297022	2315297034	2315297046	2315297059	
2315297011	2315297023	2315297035	2315297047	2315297060	
2315297012	2315297024	2315297036	2315297048	2315297069	
2315297013	2315297025	2315297037	2315297049	2315297074	

QUATUOREVO - 11.0D - Batch 2315297

2315297061	2315297062	2315297063	2315297064	2315297065	
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CLARE 12.5D - Batch 2315299

2315299001	2315299005	2315299009	2315299016	2315299020	
2315299002	2315299006	2315299011	2315299017	2315299022	
2315299003	2315299007	2315299012	2315299018	2315299023	
2315299004	2315299008	2315299014	2315299019	2315299024	

QUATUOREVO 12.5D - Batch 2315299

2315299021					
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CLARE 12.0D - Batch 2315298

2315298001	2315298012	2315298019	2315298027	2315298036	2315298043
2315298005	2315298013	2315298020	2315298028	2315298037	2315298044
2315298006	2315298014	2315298021	2315298029	2315298038	2315298045
2315298008	2315298015	2315298022	2315298030	2315298039	2315298048
2315298009	2315298016	2315298023	2315298033	2315298040	2315298051
2315298010	2315298017	2315298024	2315298034	2315298041	2315298046
2315298011	2315298018	2315298026	2315298035		

QUATUOREVO 12.0D - Batch 2315298

2315298031	2315298032				
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CLARE 18.0D - Batch 2313487

2313487001	2313487013	2313487028	2313487040	2313487054	2313487067
2313487002	2313487014	2313487029	2313487041	2313487055	2313487069
2313487003	2313487016	2313487030	2313487043	2313487056	2313487070
2313487004	2313487017	2313487031	2313487044	2313487057	2313487072
2313487005	2313487019	2313487032	2313487045	2313487058	2313487073
2313487006	2313487020	2313487033	2313487047	2313487059	2313487074
2313487007	2313487021	2313487034	2313487049	2313487060	
2313487008	2313487022	2313487035	2313487050	2313487061	
2313487010	2313487023	2313487038	2313487051	2313487062	
2313487011	2313487024	2313487039	2313487052	2313487065	
2313487012	2313487027				

2315314001	2315314007	2315314013	2315314019	2315314025	2315314031
2315314002	2315314008	2315314014	2315314020	2315314026	2315314032
2315314003	2315314009	2315314015	2315314021	2315314027	
2315314004	2315314010	2315314016	2315314022	2315314028	
2315314005	2315314011	2315314017	2315314023	2315314029	
2315314006	2315314012	2315314018	2315314024	2315314030	

QUATUOREVO - 22.5D- Batch 2315314

2315314033	2315314047	2315314065			
2315314035	2315314048	2315314068			
2315314037	2315314051	2315314069			
2315314038	2315314053	2315314070			
2315314039	2315314055				
2315314042	2315314056				
2315314043	2315314063				

QUATUOREVO - 23D- Batch 2315316

2315316001	2315316019	2315316036	2315316049	2315316064	2315316075
2315316002	2315316020	2315316037	2315316050	2315316067	2315316077
2315316003	2315316026	2315316038	2315316052	2315316068	2315316078
2315316004	2315316029	2315316039	2315316054	2315316070	2315316079
2315316005	2315316033	2315316041	2315316061	2315316071	2315316080
2315316012	2315316034	2315316044	2315316062	2315316072	
2315316013	2315316035	2315316045	2315316063	2315316073	

CLARE - 23D- Batch 2315316

2315316081	2315316083	2315316085	2315316087		
2315316082	2315316084	2315316086			

CLARE - 25D- Batch 2315647

2315647001	2315647015	2315647030	2315647048	2315647069	2315647082
2315647003	2315647016	2315647034	2315647049	2315647070	2315647083
2315647004	2315647017	2315647035	2315647050	2315647071	2315647085
2315647005	2315647018	2315647036	2315647052	2315647072	2315647025
2315647006	2315647019	2315647037	2315647053	2315647073	
2315647007	2315647020	2315647038	2315647059	2315647074	
2315647008	2315647021	2315647039	2315647062	2315647075	
2315647009	2315647022	2315647040	2315647063	2315647076	
2315647010	2315647023	2315647041	2315647064	2315647077	
2315647011	2315647024	2315647042	2315647065	2315647078	
2315647012	2315647026	2315647043	2315647066	2315647079	
2315647013	2315647027	2315647044	2315647067	2315647080	
2315647014	2315647028	2315647047	2315647068	2315647081	

CRISTAL - 17D- Batch 2315325

2315325004	2315325025	2315325035	2315325046	2315325065	2315325075
2315325010	2315325026	2315325036	2315325047	2315325066	2315325076
2315325013	2315325027	2315325037	2315325048	2315325067	2315325077
2315325014	2315325028	2315325038	2315325049	2315325068	2315325078
2315325015	2315325029	2315325039	2315325051	2315325069	2315325079
2315325016	2315325030	2315325040	2315325054	2315325070	2315325080
2315325017	2315325031	2315325041	2315325058	2315325071	2315325081
2315325018	2315325032	2315325042	2315325062	2315325072	2315325082
2315325021	2315325033	2315325044	2315325063	2315325073	
2315325024	2315325034	2315325045	2315325064	2315325074	

CRYSTAL - 24.5D- Batch 2312746

2312746001	2312746015	2312746029	2312746043	2312746057	2312746071
2312746002	2312746016	2312746030	2312746044	2312746058	2312746072
2312746003	2312746017	2312746031	2312746045	2312746059	2312746073
2312746004	2312746018	2312746032	2312746046	2312746060	2312746074
2312746005	2312746019	2312746033	2312746047	2312746061	2312746075
2312746006	2312746020	2312746034	2312746048	2312746062	2312746076
2312746007	2312746021	2312746035	2312746049	2312746063	2312746077
2312746008	2312746022	2312746036	2312746050	2312746064	2312746078
2312746009	2312746023	2312746037	2312746051	2312746065	2312746079
2312746010	2312746024	2312746038	2312746052	2312746066	2312746080
2312746011	2312746025	2312746039	2312746053	2312746067	2312746081
2312746012	2312746026	2312746040	2312746054	2312746068	2312746082
2312746013	2312746027	2312746041	2312746055	2312746069	2312746083
2312746014	2312746028	2312746042	2312746056	2312746070	2312746084
2312746085	2312746086	2312746087			

Hydrophilic acrylic intraocular lens model LUCIS

LUCIS 4.0D - Batch 2315508

2315508001	2315508005	2315508008	2315508011	2315508014	2315508017
2315508002	2315508006	2315508009	2315508012	2315508015	2315508018
2315508004	2315508007	2315508010	2315508013	2315508016	2315508019

LUCIS 8.0D - Batch 2315511

2315511001	2315511006	2315511010	2315511014	2315511018	2315511021
2315511002	2315511007	2315511012	2315511016	2315511019	2315511022
2315511004	2315511009	2315511013	2315511017	2315511020	

LUCIS 13.0D - Batch 2315529

2315529002	2315529009	2315529015	2315529020	2315529025	2315529030
2315529003	2315529010	2315529016	2315529021	2315529026	2315529032
2315529004	2315529011	2315529017	2315529022	2315529027	2315529033
2315529007	2315529012	2315529018	2315529023	2315529028	
2315529008	2315529014	2315529019	2315529024	2315529029	

LUCIS 16.5D - Batch 2315533

2315533001	2315533016	2315533031	2315533047	2315533067	2315533082
2315533002	2315533017	2315533032	2315533048	2315533068	2315533084
2315533003	2315533018	2315533033	2315533049	2315533069	2315533085
2315533004	2315533019	2315533034	2315533051	2315533070	2315533086
2315533005	2315533020	2315533035	2315533052	2315533071	2315533087
2315533006	2315533021	2315533036	2315533053	2315533072	
2315533007	2315533022	2315533037	2315533054	2315533073	
2315533008	2315533023	2315533038	2315533055	2315533074	
2315533009	2315533024	2315533039	2315533056	2315533075	
2315533010	2315533025	2315533040	2315533057	2315533076	
2315533011	2315533026	2315533041	2315533059	2315533077	
2315533012	2315533027	2315533042	2315533061	2315533078	
2315533013	2315533028	2315533044	2315533062	2315533079	
2315533014	2315533029	2315533045	2315533064	2315533080	
2315533015	2315533030	2315533046	2315533065	2315533081	

LUCIS 18 - Batch 2315535

2315535001	2315535017	2315535033	2315535049	2315535065	2315535081
2315535002	2315535018	2315535034	2315535050	2315535066	2315535082
2315535003	2315535019	2315535035	2315535051	2315535067	2315535083
2315535004	2315535020	2315535036	2315535052	2315535068	2315535084
2315535005	2315535021	2315535037	2315535053	2315535069	2315535085
2315535006	2315535022	2315535038	2315535054	2315535070	2315535086
2315535007	2315535023	2315535039	2315535055	2315535071	2315535087
2315535008	2315535024	2315535040	2315535056	2315535072	2315535088
2315535009	2315535025	2315535041	2315535057	2315535073	2315535089
2315535010	2315535026	2315535042	2315535058	2315535074	2315535090
2315535011	2315535027	2315535043	2315535059	2315535075	2315535091
2315535012	2315535028	2315535044	2315535060	2315535076	2315535092
2315535013	2315535029	2315535045	2315535061	2315535077	2315535093
2315535014	2315535030	2315535046	2315535062	2315535078	2315535094
2315535015	2315535031	2315535047	2315535063	2315535079	
2315535016	2315535032	2315535048	2315535064	2315535080	

LUCIS 19.5 - Batch 2315538

2315538001	2315538013	2315538025	2315538037	2315538049	2315538061
2315538002	2315538014	2315538026	2315538038	2315538050	2315538062
2315538003	2315538015	2315538027	2315538039	2315538051	2315538063
2315538004	2315538016	2315538028	2315538040	2315538052	2315538064
2315538005	2315538017	2315538029	2315538041	2315538053	2315538065
2315538006	2315538018	2315538030	2315538042	2315538054	2315538066
2315538007	2315538019	2315538031	2315538043	2315538055	2315538067
2315538008	2315538020	2315538032	2315538044	2315538056	2315538068
2315538009	2315538021	2315538033	2315538045	2315538057	2315538069
2315538010	2315538022	2315538034	2315538046	2315538058	2315538070
2315538011	2315538023	2315538035	2315538047	2315538059	2315538071
2315538012	2315538024	2315538036	2315538048	2315538060	2315538072

ARTIS Y PL 22.5D - Batch 2315974

2315974001	2315974008	2315974017	2315974024	2315974031	2315974038
2315974002	2315974010	2315974018	2315974025	2315974032	2315974039
2315974003	2315974012	2315974019	2315974026	2315974033	2315974040
2315974004	2315974013	2315974020	2315974027	2315974034	2315974042
2315974005	2315974014	2315974021	2315974028	2315974035	
2315974006	2315974015	2315974022	2315974029	2315974036	
2315974007	2315974016	2315974023	2315974030	2315974037	

ARTIS Y PL 22.5D - Batch 2311485

2311485001	2311485010	2311485021	2311485033	2311485042	2311485054
2311485002	2311485012	2311485024	2311485034	2311485043	2311485055
2311485003	2311485013	2311485025	2311485035	2311485044	2311485056
2311485004	2311485015	2311485026	2311485036	2311485045	
2311485005	2311485017	2311485028	2311485037	2311485050	
2311485006	2311485018	2311485029	2311485038	2311485051	
2311485007	2311485019	2311485031	2311485039	2311485052	
2311485008	2311485020	2311485032	2311485040	2311485053	

ARTIS Y PL 23D - Batch 2314557

2314557001	2314557007	2314557013	2314557019	2314557025	2314557031
2314557002	2314557008	2314557014	2314557020	2314557026	2314557032
2314557003	2314557009	2314557015	2314557021	2314557027	2314557033
2314557004	2314557010	2314557016	2314557022	2314557028	2314557034
2314557005	2314557011	2314557017	2314557023	2314557029	
2314557006	2314557012	2314557018	2314557024	2314557030	

ARTIS Y PL 23D - Batch 2315982

2315982001	2315982008	2315982020	2315982032	2315982039	2315982048
2315982002	2315982010	2315982021	2315982033	2315982041	2315982051
2315982003	2315982013	2315982023	2315982034	2315982042	2315982052
2315982004	2315982014	2315982024	2315982035	2315982043	2315982053
2315982005	2315982015	2315982027	2315982036	2315982045	2315982055
2315982006	2315982017	2315982028	2315982037	2315982046	2315982056
2315982007	2315982018	2315982031	2315982038	2315982047	2315982057
2315982037	2315982019				

ARTIS Y PL 23D - Batch 2317584

2317584001	2317584003	2317584005	2317584008	2317584010	
2317584002	2317584004	2317584006	2317584009	2317584011	

ARTIS Y PL 23D - Batch 2317741

2317741001	2317741003	2317741005	2317741007	2317741009	
2317741002	2317741004	2317741006	2317741008	2317741010	

ARTIS Y PL 23.5D - Batch 2315988

2315988001	2315988010	2315988019	2315988029	2315988038	2315988049
2315988002	2315988011	2315988020	2315988030	2315988039	2315988050
2315988003	2315988012	2315988021	2315988031	2315988040	2315988051
2315988004	2315988013	2315988022	2315988032	2315988042	2315988052
2315988005	2315988014	2315988023	2315988033	2315988043	2315988053
2315988006	2315988015	2315988024	2315988034	2315988045	2315988054
2315988007	2315988016	2315988025	2315988035	2315988046	2315988055
2315988008	2315988017	2315988026	2315988036	2315988047	2315988056
2315988009	2315988018	2315988028	2315988037	2315988048	2315988057

ARTIS Y PL 24D - Batch 2315990

2315990001	2315990011	2315990021	2315990033	2315990044	2315990054
2315990002	2315990012	2315990023	2315990034	2315990045	2315990055
2315990003	2315990013	2315990024	2315990035	2315990046	2315990056
2315990004	2315990014	2315990025	2315990036	2315990047	2315990057
2315990005	2315990015	2315990026	2315990037	2315990048	2315990058
2315990006	2315990016	2315990027	2315990038	2315990049	2315990060
2315990007	2315990017	2315990028	2315990039	2315990050	2315990061
2315990008	2315990018	2315990029	2315990040	2315990051	2315990062
2315990009	2315990019	2315990030	2315990041	2315990052	
2315990010	2315990020	2315990032	2315990043	2315990053	

ARTIS Y PL 27.5D - Batch 2314742

2314742004	2314742012	2314742021	2314742028	2314742036	2314742042
2314742006	2314742013	2314742022	2314742029	2314742037	2314742043
2314742007	2314742014	2314742024	2314742030	2314742038	2314742044
2314742009	2314742015	2314742025	2314742032	2314742039	2314742045
2314742010	2314742016	2314742026	2314742033	2314742040	2314742046
2314742011	2314742017	2314742027	2314742035	2314742041	2314742049
2314742016	2314742020				

ARTIS Y PL 27.5D - Batch 2317960

2317960001	2317960006	2317960011	2317960016	2317960021	
2317960002	2317960007	2317960012	2317960017	2317960022	
2317960003	2317960008	2317960013	2317960018	2317960024	
2317960005	2317960009	2317960014	2317960019	2317960025	
	2317960010	2317960015	2317960020	2317960026	

Preloaded hydrophobic acrylic intraocular lens model ARTIS PL E

ARTIS PLE 18D - Batch 2316404

2316404001	2316404014	2316404025	2316404033	2316404041	2316404052
2316404002	2316404015	2316404026	2316404034	2316404042	2316404053
2316404004	2316404016	2316404027	2316404035	2316404043	2316404054
2316404005	2316404017	2316404028	2316404036	2316404044	2316404057
2316404006	2316404018	2316404029	2316404037	2316404045	
2316404010	2316404021	2316404030	2316404038	2316404047	
2316404011	2316404022	2316404031	2316404039	2316404048	
2316404013	2316404023	2316404032	2316404040	2316404051	

ARTIS PLE 19.5D - Batch 2316558

2316558001	2316558009	2316558017	2316558025	2316558033	2316558041
2316558002	2316558010	2316558018	2316558026	2316558034	2316558042
2316558003	2316558011	2316558019	2316558027	2316558035	2316558043
2316558004	2316558012	2316558020	2316558028	2316558036	2316558044
2316558005	2316558013	2316558021	2316558029	2316558037	2316558045
2316558006	2316558014	2316558022	2316558030	2316558038	2316558046
2316558007	2316558015	2316558023	2316558031	2316558039	2316558047
2316558008	2316558016	2316558024	2316558032	2316558040	

ARTIS PLE 19.5D - Batch 2316559

2316559001	2316559010	2316559019	2316559027	2316559036	
2316559002	2316559011	2316559020	2316559028	2316559037	
2316559004	2316559012	2316559021	2316559029	2316559038	
2316559005	2316559013	2316559022	2316559030	2316559042	
2316559006	2316559014	2316559023	2316559031	2316559043	
2316559007	2316559015	2316559024	2316559032	2316559044	
2316559008	2316559017	2316559025	2316559033	2316559045	
2316559009	2316559018	2316559026	2316559034		

ARTIS PLE 20D - Batch 2317012

2317012001	2317012008	2317012015	2317012022	2317012029	2317012036
2317012002	2317012009	2317012016	2317012023	2317012030	2317012037
2317012003	2317012010	2317012017	2317012024	2317012031	2317012038
2317012004	2317012011	2317012018	2317012025	2317012032	
2317012005	2317012012	2317012019	2317012026	2317012033	
2317012006	2317012013	2317012020	2317012027	2317012034	
2317012007	2317012014	2317012021	2317012028	2317012035	

ARTIS PLE 20D - Batch 2317589

2317589001	2317589005	2317589009	2317589013	2317589017	
2317589002	2317589006	2317589010	2317589014	2317589018	
2317589003	2317589007	2317589011	2317589015	2317589019	
2317589004	2317589008	2317589012	2317589016		

ARTIS PLE 20.5D - Batch 2317017

2317017001	2317017010	2317017019	2317017028	2317017037	2317017046
2317017002	2317017011	2317017020	2317017029	2317017038	2317017047
2317017003	2317017012	2317017021	2317017030	2317017039	2317017048
2317017004	2317017013	2317017022	2317017031	2317017040	2317017049
2317017005	2317017014	2317017023	2317017032	2317017041	2317017050
2317017006	2317017015	2317017024	2317017033	2317017042	2317017051
2317017007	2317017016	2317017025	2317017034	2317017043	
2317017008	2317017017	2317017026	2317017035	2317017044	
2317017009	2317017018	2317017027	2317017036	2317017045	

ARTIS PLE 20.5D - Batch 2317019

2317019001	2317019007	2317019014	2317019022	2317019029	2317019035
2317019002	2317019008	2317019015	2317019023	2317019030	
2317019003	2317019009	2317019016	2317019024	2317019031	
2317019004	2317019010	2317019018	2317019025	2317019032	
2317019005	2317019012	2317019019	2317019026	2317019033	
2317019006	2317019013	2317019020	2317019028	2317019034	

ARTIS PLE 20.5D - Batch 2317740

2317740003	2317740006	2317740007			
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ARTIS PLE 21D - Batch 2317550

2317550001	2317550003	2317550005	2317550007		
2317550002	2317550004	2317550006	2317550008		

ARTIS PLE 21D - Batch 2317739

2317739001	2317739002	2317739003			
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ARTIS PLE 21.5D - Batch 2316409

2316409001	2316409019	2316409035	2316409040	2316409049	2316409057
2316409008	2316409025	2316409036	2316409041	2316409050	2316409058
2316409013	2316409029	2316409037	2316409043	2316409051	2316409059
2316409014	2316409032	2316409038	2316409044	2316409052	
2316409016	2316409034	2316409039	2316409047	2316409053	

ARTIS PLE 21.5D - Batch 2316410

2316410003	2316410012	2316410020	2316410024	2316410034	
2316410007	2316410013	2316410022	2316410025	2316410036	
2316410011	2316410018	2316410023	2316410030	2316410037	

ARTIS PLE 21.5D - Batch 2316411

2316411005	2316411010	2316411017	2316411025	2316411029	
2316411007	2316411011	2316411019	2316411027	2316411033	
2316411009	2316411016	2316411021	2316411028		

ARTIS PLE 21.5D - Batch 2317585

2317585001	2317585004	2317585007	2317585010	2317585013	
2317585002	2317585005	2317585008	2317585011	2317585014	
2317585003	2317585006	2317585009	2317585012		

ARTIS PLE 22D - Batch 2316220

2316220001	2316220008	2316220015	2316220022	2316220029	2316220036
2316220002	2316220009	2316220016	2316220023	2316220030	2316220037
2316220003	2316220010	2316220017	2316220024	2316220031	2316220038
2316220004	2316220011	2316220018	2316220025	2316220032	2316220039
2316220005	2316220012	2316220019	2316220026	2316220033	2316220040
2316220006	2316220013	2316220020	2316220027	2316220034	2316220041
2316220007	2316220014	2316220021	2316220028	2316220035	

ARTIS PLE 22.5D - Batch 2317551

2317551002	2317551004	2317551011	2317551016	2317551018	2317551020
2317551003	2317551008	2317551012	2317551017	2317551019	

ARTIS PLE 23D - Batch 2316241

2316241001	2316241007	2316241019	2316241025	2316241032	2316241039
2316241003	2316241013	2316241020	2316241026	2316241034	2316241040
2316241004	2316241015	2316241021	2316241028	2316241037	2316241041
2316241005	2316241016	2316241022	2316241029	2316241038	2316241042
2316241006	2316241018	2316241024			

ARTIS PLE 23.5D - Batch 2311436

2311436001	2311436011	2311436020			
2311436004	2311436012	2311436028			
2311436005	2311436014	2311436029			
2311436009	2311436019	2311436031			

ARTIS PLE 24.5 - Batch 2316260

2316260001	2316260009	2316260017	2316260025	2316260033	2316260041
2316260002	2316260010	2316260018	2316260026	2316260034	2316260042
2316260003	2316260011	2316260019	2316260027	2316260035	2316260043
2316260004	2316260012	2316260020	2316260028	2316260036	2316260044
2316260005	2316260013	2316260021	2316260029	2316260037	2316260045
2316260006	2316260014	2316260022	2316260030	2316260038	2316260046
2316260007	2316260015	2316260023	2316260031	2316260039	2316260047
2316260008	2316260016	2316260024	2316260032	2316260040	2316260048
					2316260049

ARTIS PLE 25 - Batch 2314867

2314867001	2314867015	2314867025	2314867034	2314867043	2314867052
2314867002	2314867016	2314867026	2314867035	2314867044	2314867053
2314867004	2314867017	2314867027	2314867036	2314867045	2314867054
2314867007	2314867018	2314867028	2314867037	2314867046	2314867055
2314867008	2314867019	2314867029	2314867038	2314867047	2314867056
2314867009	2314867020	2314867030	2314867039	2314867048	2314867057
2314867010	2314867021	2314867031	2314867040	2314867049	2314867058
2314867011	2314867023	2314867032	2314867041	2314867050	2314867059
2314867012	2314867024	2314867033	2314867042	2314867051	2314867060

Appendix 2:

CUSTOMER RESPONSE FORM - SAFETY NOTICE - CRISTALENS INDUSTRIE

Reference: FSN_RC_00641

Date: December 19, 2023

Medical devices concerned: Hydrophilic acrylic intraocular lenses CLARE, QUATUOREVO, CRISTAL, LUCIS
Preloaded hydrophobic acrylic intraocular lenses ARTIS Y PL, ARTIS PL E

Please complete and return this form immediately by e-mail to materiovigilance@crystalens.fr.

I have read the safety notice dated December 19, 2023 and checked my stock. We will return the affected medical devices as soon as possible.

I have read the safety notice of December 19, 2023 and checked my stock. I confirm that my establishment has no medical devices concerned by this safety notice.

Signing this document confirms that you have read and understood the information contained in this communication.

Company name:

Name and surname of manager:

Position:

Date:

Signature & company stamp :
