

France, Croix, on the 26th of June 2018

██████████
██████████
██████████
info@surgiris.com

SAFETY NOTIFICATION
Impact protection for SURGIRIS surgical lights

Dear Partner,

We are sending you this letter to inform you that SURGIRIS SAS has put in place a safety action for its surgical lights. This action is our response to the identification of a risk whereby certain components of the lights are susceptible to breaking when impacted by another object.

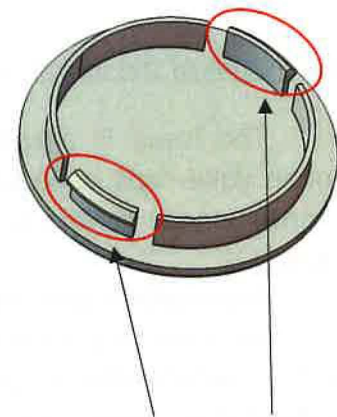
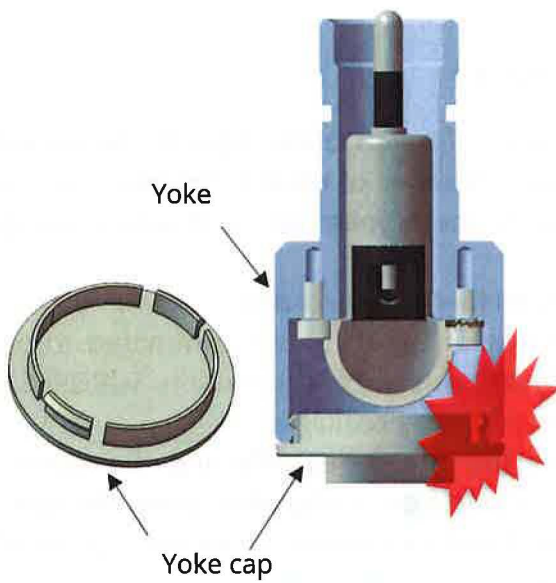
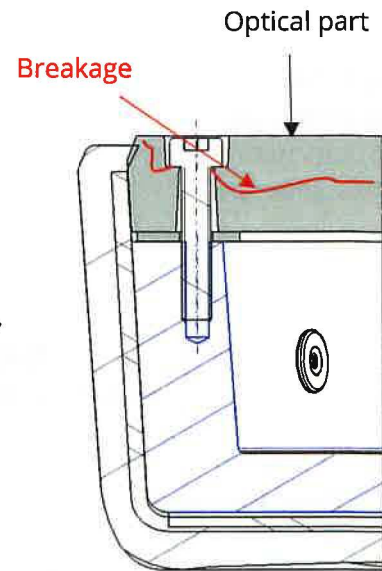
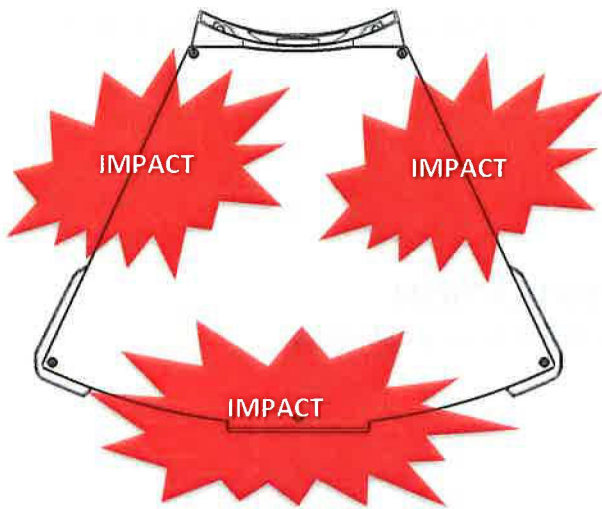
Description of the incident and causes analysis:

The issue is a sporadic phenomenon. Broken outer optical components and broken yoke caps have been reported by a number of establishments in a co-related manner. Under certain particular conditions, these yoke caps and optical components break.

No health-related consequence has so far been recorded.

As a manufacturer of medical devices, SURGIRIS SAS is committed to providing products which offer a high level of quality and safety. For this reason, SURGIRIS SAS has conducted an investigation into the causes of these breakages.

This in-depth analysis found that the breakages affecting the outer optical components and yoke caps resulted from impacts occurring while using the lights, when the lighthouse comes into contact with a hard surface (an arm or another lighthouse).



Concerned devices:

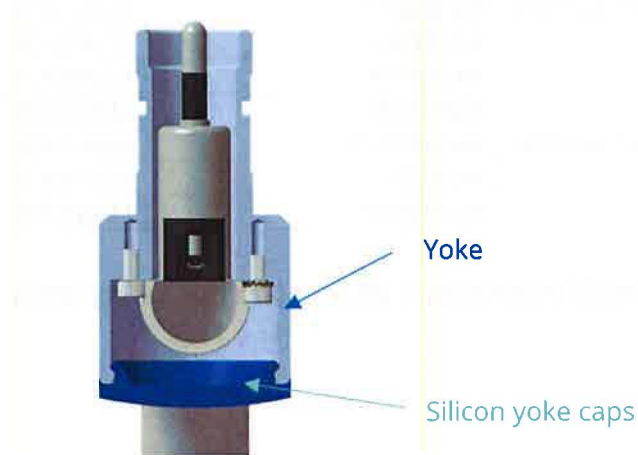
The phenomenon affects the outer optical components and yoke caps fitted to all models and versions of SURGIRIS SAS surgical lights (except X1 light for optical part):

Model	Reference on product label	Description on product label
LEDVISION 202 (distributed via KARL STORZ SE & Co. KG)	WL202DY1	LEDVISION 202 DY
	WL202DYV1	LEDVISION 202 DY VIDEO
	WL202SY1	LEDVISION 202 SY
	WL202SYV1	LEDVISION 202 SY VIDEO
LEDVISION 203 (distributed via KARL STORZ SE & Co. KG)	WL203DY1	LEDVISION 203 DY
	WL203DYV1	LEDVISION 203 DY VIDEO
	WL203SY1	LEDVISION 203 SY
LEDVISION 302 (distributed via KARL STORZ SE & Co. KG)	WL203SYV1	LEDVISION 203 SY VIDEO
	WL302DY1	LEDVISION 302 DY
	WL302DYV1	LEDVISION 302 DY VIDEO
	WL302SY1	LEDVISION 302 SY
LEDVISION 303 (distributed via KARL STORZ SE & Co. KG)	WL302SYV1	LEDVISION 302 SY VIDEO
	WL303DY1	LEDVISION 303 DY
	WL303DYV1	LEDVISION 303 DY VIDEO
	WL303SY1	LEDVISION 303 SY
	WL303SYV1	LEDVISION 303 SY VIDEO

A list of concerned LEDVISION devices is attached to this safety letter.

Safety action:

In order to prevent these situations occurring, SURGIRIS SAS has designed different protection systems that can withstand the impacts: an aluminium frame around the optical components and silicon yoke caps. These protection systems absorb the impacts and ensure that the optical components and yoke caps do not break.



Action to be taken by your establishment:

To address the current situation, SURGIRIS SAS has decided to inform all its customers for preventive purposes.

To prevent all risks, we are asking you to check the condition of the optical components and yoke caps on all your SURGIRIS surgical lights, following the procedure described in the appendix.

The new impact protection systems are available on request from our Customer Services department, and are identified by the following reference numbers:

Complete kits of new optical components:

Model	References
LEDVISION 302	WLAS-1003
LEDVISION 303	WLAS-1004
LEDVISION 202	WLAS-1005
LEDVISION 203	WLAS-1006

Complete kits of new silicon yoke caps:

Kits	References
Kit blue yoke cap (2 white + 1 blue yoke caps)	WLAS-0251
Kit orange yoke cap (2 white + 1 orange yoke caps)	WLAS-0252
Kit yellow yoke cap (2 white + 1 yellow yoke caps)	WLAS-0253

If, while performing the check in accordance with the attached procedure, you notice any optical components and/or yoke caps which are in poor condition, please complete the appended customer response form and return it to us as soon as possible by fax to +33 (0)3.20.95.40.19. or by email to: sav@surgiris.com



Design that cares

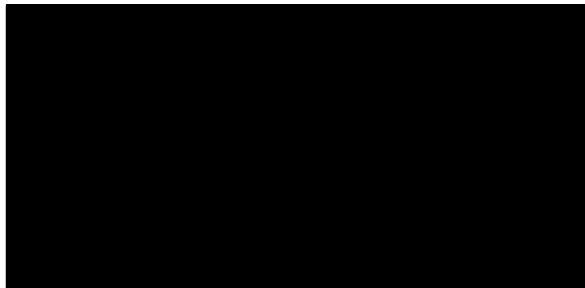
Precautions:

Furthermore, and in all cases, all users of SURGIRIS lights should be informed and reminded that, although SURGIRIS lights are designed to be used in a medical setting and in some cases in emergency care settings, these devices are sensitive to impacts and consequently that care should be taken to avoid impacts wherever possible.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) has been informed of this safety notification.

Could you please ensure that every potential user and any other person concerned with the implementation of this safety notification is informed of its contents.

If you require additional information about this safety notification, please contact *Mr BERTINCHANT* from our Customer Services department, *on +33 (0)3 20 16 53 40* or via email: sav@surgiris.com.



Attachments :

-List of concerned LEDVISION devices

Appendix

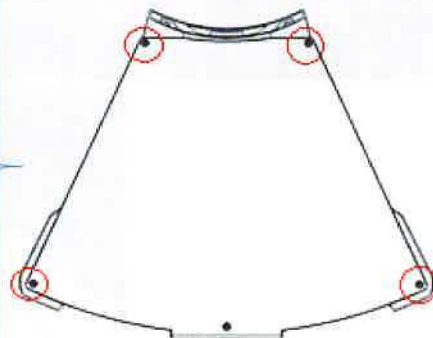
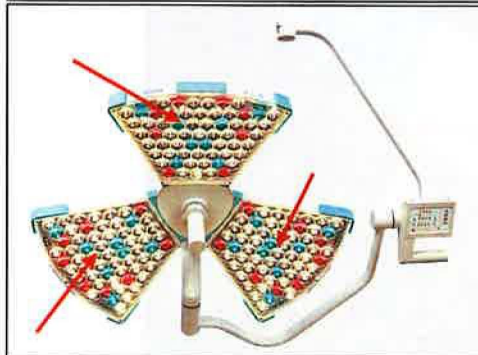
1. Check optical parts

1.1 Localisation of breakages

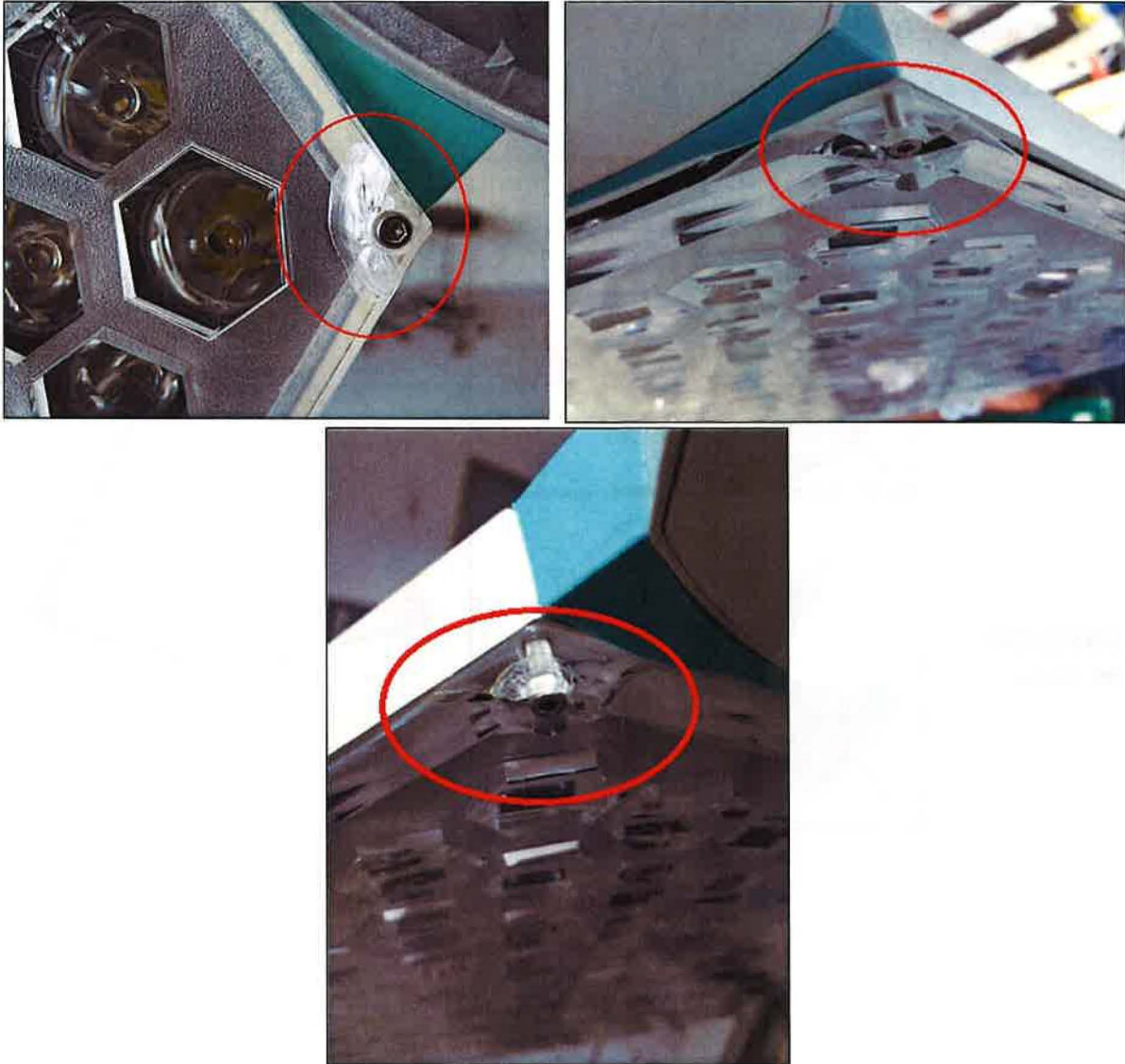
**LEDVISION
300 serie**



**LEDVISION
200 serie**



1.2 Defective optical parts

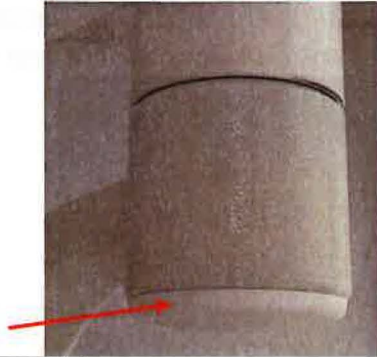


These optical parts are broken.

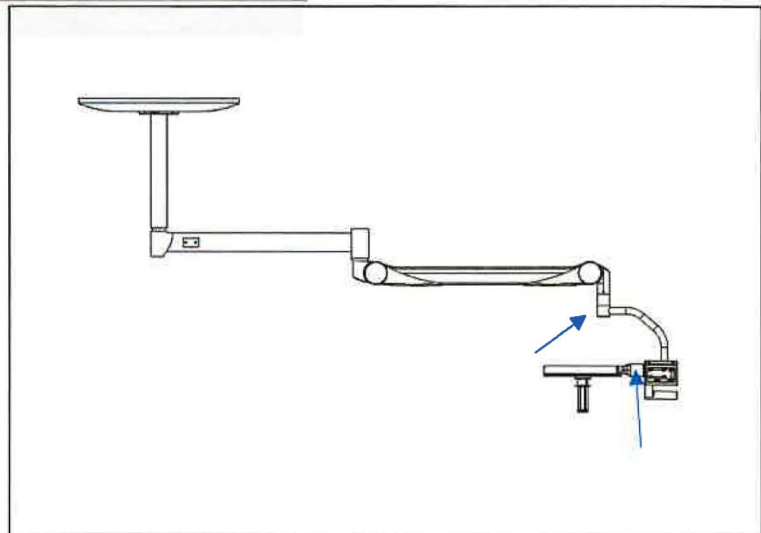
They are non-conform and have to be replaced.

2. Check of yoke caps

2.1 Localisation of the yoke caps on the lights

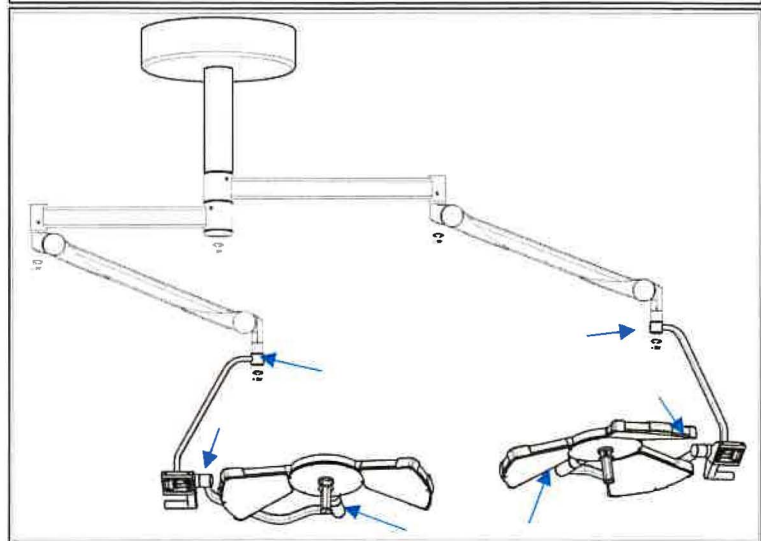


**Example:
Single Configuration
- one yoke:**



**LEDVISION
300 serie
LEDVISION
200 serie**

**Example:
Double
configuration-two
yokes:**



2.2 Defective yoke caps

If any yoke caps are **broken or cracked** (broken securing tabs in particular) and/or **are not properly secured in place** and/or **there is play between the yoke cap and the yoke end-piece**, then these yoke caps **do not conform and must be replaced**.



3. Notification to SURGIRIS

Via fax: +33/(0)3 20 95 40 19

To the attention to Mrs FORMENTEL, quality and regulatory affairs manager

I hereby declare that I have received the safety notification regarding the new protection systems for SURGIRIS surgical lights, dated 26th of June 2018, and the inspection procedure.

I declare that I have conducted a verification of the lights in accordance with the procedure indicated and that I have notified SURGIRIS of the condition of all of its equipment within my establishment.

Establishment:

Date:

Name:

Function:

Signature:

Stamp:

LIST OF CONCERNED LEDVISION DEVICES

Device reference	Serial number	Old version of optical part	Old version of plastic yoke end cap	Device reference	Serial number	Old version of optical part	Old version of plastic yoke end cap
WL202DY1	C.16.01.0059	✓	✓	WL202DYV1	D.16.04.0067	✓	✓
WL202DY1	C.16.01.0061	✓	✓	WL202DYV1	E.16.07.0068	✓	
WL202DY1	C.16.01.0060	✓	✓	WL202DYV1	E.16.07.0069	✓	
WL202DY1	B.15.04.0014	✓	✓	WL202DYV1	B.15.07.0026	✓	✓
WL202DY1	B.15.07.0024	✓	✓	WL202DYV1	B.15.07.0020	✓	✓
WL202DY1	B.15.10.0046	✓	✓	WL202DYV1	D.16.03.0065	✓	✓
WL202DY1	B.15.07.0030	✓	✓	WL202DYV1	C.15.12.0058	✓	✓
WL202DY1	B.15.07.0029	✓	✓	WL202DYV1	B.15.07.0027	✓	✓
WL202DY1	C.15.12.0057	✓	✓	WL202DYV1	F.16.10.0078	✓	
WL202DY1	C.15.12.0056	✓	✓	WL202DYV1	F.16.10.0077	✓	
WL202DY1	C.16.02.0063	✓	✓	WL202DYV1	F.16.10.0071	✓	
WL202DY1	B.15.07.0023	✓	✓	WL202DYV1	F.16.10.0073	✓	
WL202DY1	B.15.07.0025	✓	✓	WL202DYV1	F.16.10.0079	✓	
WL202DY1	B.15.07.0017	✓	✓	WL202DYV1	F.16.10.0072	✓	
WL202DY1	B.15.07.0018	✓	✓	WL202DYV1	F.16.10.0080	✓	
WL202DY1	A.14.11.0007	✓	✓	WL202SY1	C.16.03.0064	✓	✓
WL202DY1	A.15.01.0008	✓	✓	WL202SYV1	C.16.01.0062	✓	✓
WL202DY1	A.15.03.0009	✓	✓	WL202SYV1	D.16.08.0070	✓	
WL202DY1	C.15.12.0055	✓	✓	WL202SYV1	B.15.10.0047	✓	✓
WL202DY1	D.16.11.0082	✓		WL202SYV1	E.16.11.0081	✓	
WL202DY1	D.16.10.0074	✓		WL203DY1	B.15.11.0036	✓	✓
WL202DY1	D.16.10.0076	✓		WL203DY1	A.14.07.0005	✓	✓
WL202DY1	D.16.10.0075	✓		WL203DY1	B.15.11.0037	✓	✓
WL202DY1	B.15.07.0028	✓	✓	WL203DY1	D.16.11.0075	✓	
WL202DY1	B.15.07.0034	✓	✓	WL203DY1	B.15.10.0027	✓	✓
WL202DY1	B.15.07.0031	✓	✓	WL203DY1	B.15.11.0029	✓	✓
WL202DY1	B.15.07.0033	✓	✓	WL203DY1	B.15.11.0030	✓	✓
WL202DY1	B.15.07.0032	✓	✓	WL203DY1	B.15.10.0028	✓	✓
WL202DY1	B.15.08.0040	✓		WL203DY1	B.15.04.0016	✓	✓
WL202DY1	B.15.08.0041	✓		WL203DY1	A.15.02.0010	✓	✓
WL202DY1	B.15.08.0038	✓		WL203DY1	B.15.10.0025	✓	✓
WL202DY1	B.15.08.0039	✓	✓	WL203DY1	A.14.06.0004	✓	✓
WL202DY1	B.15.08.0042	✓	✓	WL203DY1	B.16.04.0044	✓	✓
WL202DY1	B.15.08.0043	✓	✓	WL203DY1	B.16.04.0045	✓	✓
WL202DY1	B.15.08.0037	✓	✓	WL203DY1	C.16.07.0061	✓	
WL202DY1	B.15.08.0036	✓	✓	WL203DY1	C.16.07.0058	✓	
WL202DY1	B.15.08.0035	✓	✓	WL203DY1	B.15.07.0021	✓	✓
WL202DYV1	C.15.11.0053	✓	✓	WL203DY1	B.15.07.0020	✓	✓

LIST OF CONCERNED LEDVISION DEVICES

Device reference	Serial number	Old version of optical part	Old version of plastic yoke end cap	Device reference	Serial number	Old version of optical part	Old version of plastic yoke end cap
WL202DYV1	C.15.11.0052	✓	✓	WL203SY1	C.16.07.0047	✓	
WL202DYV1	A.14.07.0006	✓	✓	WL203SY1	C.16.07.0054	✓	
WL202DYV1	C.15.11.0054	✓	✓	WL203SY1	C.16.07.0052	✓	
WL202DYV1	F.16.11.0083	✓		WL203SY1	C.16.07.0049	✓	
WL202DYV1	D.15.11.0048	✓	✓	WL203SY1	C.16.07.0048	✓	
WL202DYV1	D.15.11.0050	✓	✓	WL203SY1	C.16.07.0053	✓	
WL202DYV1	D.15.11.0051	✓	✓	WL203SY1	B.16.01.0040	✓	✓
WL202DYV1	D.15.11.0049	✓	✓	WL203SY1	C.16.07.0056	✓	
WL202DYV1	B.15.04.0015	✓	✓	WL203SY1	C.16.07.0057	✓	
WL202DYV1	A.15.03.0013	✓	✓	WL203SY1	C.16.08.0062	✓	
WL202DYV1	A.14.06.0005	✓	✓	WL203SY1	B.15.10.0026	✓	✓
WL202DYV1	D.16.04.0066	✓	✓	WL203SY1	D.16.11.0073	✓	
WL203DY1	B.16.03.0043	✓	✓	WL203SYV1	D.16.07.0050	✓	
WL203DY1	B.15.06.0018	✓	✓	WL203SYV1	C.16.03.0042	✓	✓
WL203DY1	B.15.07.0024	✓	✓	WL203SYV1	D.16.04.0099	✓	
WL203DY1	A.15.03.0014	✓	✓	WL203SYV1	D.16.07.0060	✓	
WL203DY1	B.15.12.0039	✓	✓	WL302DY1	C.15.11.0014	✓	✓
WL203DY1	B.15.07.0022	✓	✓	WL302DY1	C.16.02.0019	✓	✓
WL203DY1	D.16.10.0066	✓		WL302DY1	D.16.11.0024	✓	
WL203DY1	D.16.10.0068	✓		WL302DY1	C.16.01.0015	✓	✓
WL203DY1	B.15.12.0038	✓	✓	WL302DY1	C.16.01.0016	✓	✓
WL203DY1	D.16.10.0063	✓		WL302DY1	C.16.01.0017	✓	✓
WL203DY1	D.16.10.0067	✓		WL302DYV1	D.16.12.0028	✓	
WL203DY1	D.16.10.0065	✓		WL302DYV1	D.16.11.0022	✓	
WL203DY1	D.16.10.0064	✓		WL302DYV1	C.16.02.0016	✓	✓
WL203DY1	B.15.11.0035	✓	✓	WL302DYV1	D.16.12.0027	✓	
WL203DY1	D.16.10.0069	✓		WL302DYV1	A.15.02.0001	✓	✓
WL203DY1	D.16.10.0070	✓		WL302DYV1	B.15.05.0006	✓	✓
WL203DY1	D.16.10.0072	✓		WL302DYV1	B.15.05.0008	✓	✓
WL203DY1	D.16.10.0071	✓		WL302DYV1	C.16.03.0021	✓	✓
WL203DYV1	A.14.11.0006	✓	✓	WL302DYV1	B.15.06.0009	✓	✓
WL203DYV1	B.15.06.0019	✓	✓	WL302DYV1	D.16.11.0023	✓	
WL203DYV1	A.14.11.0007	✓	✓	WL302DYV1	B.15.07.0011	✓	✓
WL203DYV1	A.14.11.0008	✓	✓	WL302DYV1	B.15.07.0012	✓	✓
WL203DYV1	B.15.07.0023	✓	✓	WL302SY1	B.15.06.0010	✓	✓
WL203DYV1	A.15.02.0013	✓	✓	WL302SYV1	B.15.05.0007	✓	✓
WL203DYV1	D.16.11.0074	✓		WL303DY1	C.15.11.0033	✓	✓
WL203DYV1	A.15.01.0009	✓	✓	WL303DY1	B.15.07.0018	✓	✓

LIST OF CONCERNED LEDVISION DEVICES

Device reference	Serial number	Old version of optical part	Old version of plastic yoke end cap	Device reference	Serial number	Old version of optical part	Old version of plastic yoke end cap
WL303DY1	D.16.12.0066	✓		WL303DYV1	B.15.07.0020	✓	
WL303DY1	B.15.07.0019	✓	✓	WL303DYV1	B.15.10.0024	✓	
WL303DY1	D.16.11.0059	✓		WL303DYV1	B.15.10.0028	✓	
WL303DY1	C.16.02.0041	✓	✓	WL303DYV1	B.15.07.0020		✓
WL303DY1	D.16.12.0065	✓		WL303DYV1	B.15.10.0024		✓
WL303DY1	C.16.01.0035	✓	✓	WL303DYV1	B.15.10.0028		✓
WL303DY1	C.16.01.0036	✓	✓	WL303SY1	B.15.06.0012	✓	✓
WL303DY1	C.16.01.0037	✓	✓	WL303SY1	B.15.05.0008	✓	✓
WL303DY1	A.15.03.0002	✓	✓	WL303SYV1	WL303SYV1	✓	✓
WL303DY1	B.15.05.0009	✓	✓				
WL303DY1	B.15.05.0004	✓	✓				
WL303DY1	C.16.03.0056	✓	✓				
WL303DY1	B.15.06.0010	✓	✓				
WL303DY1	C.16.02.0039	✓	✓				
WL303DY1	D.16.11.0060	✓					
WL303DY1	B.15.10.0025	✓	✓				
WL303DY1	B.15.10.0022	✓	✓				
WL303DY1	B.15.10.0026	✓	✓				
WL303DY1	B.15.10.0030	✓	✓				
WL303DY1	B.15.07.0021	✓	✓				
WL303DYV1	C.15.11.0034	✓	✓				
WL303DYV1	C.16.01.0038	✓	✓				
WL303DYV1	C.12.06.0055	✓	✓				
WL303DYV1	D.16.12.0064	✓					
WL303DYV1	B.15.05.0007	✓	✓				
WL303DYV1	B.15.05.0006	✓	✓				
WL303DYV1	C.16.04.0058	✓	✓				
WL303DYV1	C.16.04.0057	✓	✓				
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WL303DYV1	E.16.12.0061	✓					
WL303DYV1	E.16.12.0062	✓					
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WL303DYV1	C.16.02.0052	✓	✓				
WL303DYV1	C.16.02.0051	✓	✓				