

EC DECLARATION OF CONFORMITY ACCORDING TO DIRECTIVE 93/42/EEC

This declaration is issued under the sole responsibility of Cutting Edge S.A.S. as manufacturer of the mentioned products.

DEVICES CATEGORY	Posterior-chamber intraocular lenses, pseudophakic
GMDN CODE	35658
PRODUCTS	LuxSmart models : SMART, YSMART
CLASS	IIb, Rule 8, according to Directive 93/42/EEC Annex IX
MANUFACTURER	Cutting Edge S.A.S. Immeuble Le Nobel 770 rue Alfred Nobel 34000 Montpellier France

Above products are developed and manufactured in compliance with Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 and the applicable European harmonized standards.

NOTIFIED BODY	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany
	Notified Body number: 0197
QUALITY SYSTEM CERTIFICATE	EN ISO 13485:2016 "Design and development, manufacture and distribution of acrylic intraocular lenses and distribution of intraocular lenses and ophthalmic surgical devices." Number: SX 60146578 0001 Expires on: 2022-12-07
EC CERTIFICATE	Number: HD 60148953 0001 Expires on: 2024-05-26
DECLARATION REVISION INDEX	A

We hereby declare the conformity of the above mentioned products with the Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, Annex II "Full quality assurance system", excluding section 4.

This Declaration of Conformity expires on: 2022-12-07

Date and
Signature

2020 / 05 / 06 

Sandrine BONACHE
Quality and Regulatory Affairs Manager - Cutting Edge S.A.S



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LuxSmart					
MODEL "SMART"			MODEL "YSMART"		
REF	DESCRIPTION	GTIN	REF	DESCRIPTION	GTIN
SMART+00.00D	LUXSMART PRELOAD CRYSTAL 00.00D	3665493026608	YSMART+00.00D	LUXSMART PRELOADED 00.00D	3665493027209
SMART+01.00D	LUXSMART PRELOAD CRYSTAL 01.00D	3665493026592	YSMART+01.00D	LUXSMART PRELOADED 01.00D	3665493027193
SMART+02.00D	LUXSMART PRELOAD CRYSTAL 02.00D	3665493026585	YSMART+02.00D	LUXSMART PRELOADED 02.00D	3665493027186
SMART+03.00D	LUXSMART PRELOAD CRYSTAL 03.00D	3665493026578	YSMART+03.00D	LUXSMART PRELOADED 03.00D	3665493027179
SMART+04.00D	LUXSMART PRELOAD CRYSTAL 04.00D	3665493026561	YSMART+04.00D	LUXSMART PRELOADED 04.00D	3665493027162
SMART+05.00D	LUXSMART PRELOAD CRYSTAL 05.00D	3665493026554	YSMART+05.00D	LUXSMART PRELOADED 05.00D	3665493027155
SMART+06.00D	LUXSMART PRELOAD CRYSTAL 06.00D	3665493026547	YSMART+06.00D	LUXSMART PRELOADED 06.00D	3665493027148
SMART+07.00D	LUXSMART PRELOAD CRYSTAL 07.00D	3665493026530	YSMART+07.00D	LUXSMART PRELOADED 07.00D	3665493027131
SMART+08.00D	LUXSMART PRELOAD CRYSTAL 08.00D	3665493026523	YSMART+08.00D	LUXSMART PRELOADED 08.00D	3665493027124
SMART+09.00D	LUXSMART PRELOAD CRYSTAL 09.00D	3665493026516	YSMART+09.00D	LUXSMART PRELOADED 09.00D	3665493027117
SMART+10.00D	LUXSMART PRELOAD CRYSTAL 10.00D	3665493026509	YSMART+10.00D	LUXSMART PRELOADED 10.00D	3665493027100
SMART+10.50D	LUXSMART PRELOAD CRYSTAL 10.50D	3665493026493	YSMART+10.50D	LUXSMART PRELOADED 10.50D	3665493027094
SMART+11.00D	LUXSMART PRELOAD CRYSTAL 11.00D	3665493026486	YSMART+11.00D	LUXSMART PRELOADED 11.00D	3665493027087
SMART+11.50D	LUXSMART PRELOAD CRYSTAL 11.50D	3665493026479	YSMART+11.50D	LUXSMART PRELOADED 11.50D	3665493027070
SMART+12.00D	LUXSMART PRELOAD CRYSTAL 12.00D	3665493026462	YSMART+12.00D	LUXSMART PRELOADED 12.00D	3665493027063
SMART+12.50D	LUXSMART PRELOAD CRYSTAL 12.50D	3665493026455	YSMART+12.50D	LUXSMART PRELOADED 12.50D	3665493027056
SMART+13.00D	LUXSMART PRELOAD CRYSTAL 13.00D	3665493026448	YSMART+13.00D	LUXSMART PRELOADED 13.00D	3665493027049
SMART+13.50D	LUXSMART PRELOAD CRYSTAL 13.50D	3665493026431	YSMART+13.50D	LUXSMART PRELOADED 13.50D	3665493027032
SMART+14.00D	LUXSMART PRELOAD CRYSTAL 14.00D	3665493026424	YSMART+14.00D	LUXSMART PRELOADED 14.00D	3665493027025
SMART+14.50D	LUXSMART PRELOAD CRYSTAL 14.50D	3665493026417	YSMART+14.50D	LUXSMART PRELOADED 14.50D	3665493027018
SMART+15.00D	LUXSMART PRELOAD CRYSTAL 15.00D	3665493026400	YSMART+15.00D	LUXSMART PRELOADED 15.00D	3665493027001
SMART+15.50D	LUXSMART PRELOAD CRYSTAL 15.50D	3665493026394	YSMART+15.50D	LUXSMART PRELOADED 15.50D	3665493026998
SMART+16.00D	LUXSMART PRELOAD CRYSTAL 16.00D	3665493026387	YSMART+16.00D	LUXSMART PRELOADED 16.00D	3665493026981
SMART+16.50D	LUXSMART PRELOAD CRYSTAL 16.50D	3665493026370	YSMART+16.50D	LUXSMART PRELOADED 16.50D	3665493026974
SMART+17.00D	LUXSMART PRELOAD CRYSTAL 17.00D	3665493026363	YSMART+17.00D	LUXSMART PRELOADED 17.00D	3665493026967
SMART+17.50D	LUXSMART PRELOAD CRYSTAL 17.50D	3665493026356	YSMART+17.50D	LUXSMART PRELOADED 17.50D	3665493026950
SMART+18.00D	LUXSMART PRELOAD CRYSTAL 18.00D	3665493026349	YSMART+18.00D	LUXSMART PRELOADED 18.00D	3665493026943



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LuxSmart					
MODEL "SMART"			MODEL "YSMART"		
REF	DESCRIPTION	GTIN	REF	DESCRIPTION	GTIN
SMART+18.50D	LUXSMART PRELOAD CRYSTAL 18.50D	3665493026332	YSMART+18.50D	LUXSMART PRELOADED 18.50D	3665493026936
SMART+19.00D	LUXSMART PRELOAD CRYSTAL 19.00D	3665493026325	YSMART+19.00D	LUXSMART PRELOADED 19.00D	3665493026929
SMART+19.50D	LUXSMART PRELOAD CRYSTAL 19.50D	3665493026318	YSMART+19.50D	LUXSMART PRELOADED 19.50D	3665493026912
SMART+20.00D	LUXSMART PRELOAD CRYSTAL 20.00D	3665493026301	YSMART+20.00D	LUXSMART PRELOADED 20.00D	3665493026905
SMART+20.50D	LUXSMART PRELOAD CRYSTAL 20.50D	3665493026295	YSMART+20.50D	LUXSMART PRELOADED 20.50D	3665493026899
SMART+21.00D	LUXSMART PRELOAD CRYSTAL 21.00D	3665493026288	YSMART+21.00D	LUXSMART PRELOADED 21.00D	3665493026882
SMART+21.50D	LUXSMART PRELOAD CRYSTAL 21.50D	3665493026271	YSMART+21.50D	LUXSMART PRELOADED 21.50D	3665493026875
SMART+22.00D	LUXSMART PRELOAD CRYSTAL 22.00D	3665493026264	YSMART+22.00D	LUXSMART PRELOADED 22.00D	3665493026868
SMART+22.50D	LUXSMART PRELOAD CRYSTAL 22.50D	3665493026257	YSMART+22.50D	LUXSMART PRELOADED 22.50D	3665493026851
SMART+23.00D	LUXSMART PRELOAD CRYSTAL 23.00D	3665493026240	YSMART+23.00D	LUXSMART PRELOADED 23.00D	3665493026844
SMART+23.50D	LUXSMART PRELOAD CRYSTAL 23.50D	3665493026233	YSMART+23.50D	LUXSMART PRELOADED 23.50D	3665493026837
SMART+24.00D	LUXSMART PRELOAD CRYSTAL 24.00D	3665493026226	YSMART+24.00D	LUXSMART PRELOADED 24.00D	3665493026820
SMART+24.50D	LUXSMART PRELOAD CRYSTAL 24.50D	3665493026219	YSMART+24.50D	LUXSMART PRELOADED 24.50D	3665493026813
SMART+25.00D	LUXSMART PRELOAD CRYSTAL 25.00D	3665493026202	YSMART+25.00D	LUXSMART PRELOADED 25.00D	3665493026806
SMART+25.50D	LUXSMART PRELOAD CRYSTAL 25.50D	3665493026196	YSMART+25.50D	LUXSMART PRELOADED 25.50D	3665493026790
SMART+26.00D	LUXSMART PRELOAD CRYSTAL 26.00D	3665493026189	YSMART+26.00D	LUXSMART PRELOADED 26.00D	3665493026783
SMART+26.50D	LUXSMART PRELOAD CRYSTAL 26.50D	3665493026172	YSMART+26.50D	LUXSMART PRELOADED 26.50D	3665493026776
SMART+27.00D	LUXSMART PRELOAD CRYSTAL 27.00D	3665493026165	YSMART+27.00D	LUXSMART PRELOADED 27.00D	3665493026769
SMART+27.50D	LUXSMART PRELOAD CRYSTAL 27.50D	3665493026158	YSMART+27.50D	LUXSMART PRELOADED 27.50D	3665493026752
SMART+28.00D	LUXSMART PRELOAD CRYSTAL 28.00D	3665493026141	YSMART+28.00D	LUXSMART PRELOADED 28.00D	3665493026745
SMART+28.50D	LUXSMART PRELOAD CRYSTAL 28.50D	3665493026134	YSMART+28.50D	LUXSMART PRELOADED 28.50D	3665493026738
SMART+29.00D	LUXSMART PRELOAD CRYSTAL 29.00D	3665493026127	YSMART+29.00D	LUXSMART PRELOADED 29.00D	3665493026721
SMART+29.50D	LUXSMART PRELOAD CRYSTAL 29.50D	3665493026110	YSMART+29.50D	LUXSMART PRELOADED 29.50D	3665493026714
SMART+30.00D	LUXSMART PRELOAD CRYSTAL 30.00D	3665493026103	YSMART+30.00D	LUXSMART PRELOADED 30.00D	3665493026707
SMART+30.50D	LUXSMART PRELOAD CRYSTAL 30.50D	3665493026096	YSMART+30.50D	LUXSMART PRELOADED 30.50D	3665493026690
SMART+31.00D	LUXSMART PRELOAD CRYSTAL 31.00D	3665493026089	YSMART+31.00D	LUXSMART PRELOADED 31.00D	3665493026683
SMART+31.50D	LUXSMART PRELOAD CRYSTAL 31.50D	3665493026082	YSMART+31.50D	LUXSMART PRELOADED 31.50D	3665493026676
SMART+32.00D	LUXSMART PRELOAD CRYSTAL 32.00D	3665493026075	YSMART+32.00D	LUXSMART PRELOADED 32.00D	3665493026669

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LuxSmart					
MODEL "SMART"			MODEL "YSMART"		
REF	DESCRIPTION	GTIN	REF	DESCRIPTION	GTIN
SMART+32.50D	LUXSMART PRELOAD CRYSTAL 32.50D	3665493026035	YSMART+32.50D	LUXSMART PRELOADED 32.50D	3665493026639
SMART+33.00D	LUXSMART PRELOAD CRYSTAL 33.00D	3665493026073	YSMART+33.00D	LUXSMART PRELOADED 33.00D	3665493026677
SMART+33.50D	LUXSMART PRELOAD CRYSTAL 33.50D	3665493026028	YSMART+33.50D	LUXSMART PRELOADED 33.50D	3665493026622
SMART+34.00D	LUXSMART PRELOAD CRYSTAL 34.00D	3665493026011	YSMART+34.00D	LUXSMART PRELOADED 34.00D	3665493026615