

EC Certification



FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

SAUFLON PHARMACEUTICALS LIMITED

49-53 York Street, Twickenham, Middlesex. TW1 3LP, United Kingdom

Sterile soft contact lenses
Sterile contact lens care solutions, eye washes, eye drops, nasal drops and other ancillary products,
as per the attached product schedule

Certificate Number: 041 CE
Initial Certification Date: 23 July 1997
Certificate Effective Date: 17 October 2014
Certificate Expiry Date: 22 July 2017



Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

PRODUCT SCHEDULE FOR CERTIFICATE 041 CE SAUFLON PHARMACEUTICALS LIMITED



SAUFLON NAME	CODE	GENERIC NAME
ALL IN ONE LIGHT	LIT	MULTIPURPOSE SOLUTION
SAUFLON MULTIPURPOSE	SMRF	MULTIPURPOSE SOLUTION
DELTA CLEANER	LOBOB	CLEANING SOLUTION
DELTA PLUS DISINFECTING, SOAKING, WETTING SOLUTION	PLUS (GP RANGE)	MULTIPURPOSE SOLUTION
PRESERVED SALINE	SALPRE	SALINE SOLUTION
PRESERVATIVE FREE DAILY CLEANER	DC	DAILY CLEANER
PLATINUM DISC (ONE STEP PEROXIDE)	PT	PEROXIDE NEUTRALISING DISC
CYCLEAN	CYC	MULTIPURPOSE SOLUTION
NASOSAL™	NASAL	NASAL DROPS
COMFORTVUE/MULTIVUE	VUE	MULTIPURPOSE SOLUTION
COMFORT DROPS	CD1	CONTACT LENS EYE DROPS
PRESERVATIVE FREE SALINE	PFS	SALINE
SYNERGI	SYN	MULTI PURPOSE SOLUTION
EYE WASH SOLUTION		EYE WASH SOLUTION
EYE MOISTURISING DROPS WITH VITAMIN A		EYE MOIST
HY-CARE MULTIPURPOSE SOLUTION		MULTI PURPOSE SOLUTION HY-CARE CONTACT LENS MULTI PURPOSE SOLUTION FOR ALL SIZES INCLUDING 60,120, 250, 360, 3X360 AND 380ml
EYE WASH WITH HYALURONATE		EYE WASH SOLUTION
COMFORT DROPS WITH HYALURONATE		COMFORT EYE DROPS
EYE MOIST		COMFORT EYE DROPS
SYNERGI GP		MULTI PURPOSE SOLUTION

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Brian Johnson ~ Authorized Signatory

PRODUCT SCHEDULE FOR CERTIFICATE 041 CE SAUFLON PHARMACEUTICALS LIMITED



SAUFLON	SAUFLON NAME	GENERIC NAME
FILCON 1B (METHAFILCON A) WITH UV FILTER	SAUFLON 55 UV LENS CLEAR COMFORT LENS NEW DAY LENS	SOFT CONTACT LENS
FILCON IV 1 WITH AQUATRACT	BIOCLEAR TORIC BIOCLEAR BIOCLEAR 1 – DAY	SOFT CONTACT LENS
FILCON 1B POLYMACON TFF555560	SAUFLON 38	SOFT CONTACT LENS
FILCON 1B WITH ULTRA VIOLET INHIBITOR TF-F55UV	SAUFLON UV58 FREQUENCY UV 58 OPTIVIEW UV58 ULTRASOFT UV58 VD 55UV	
SILICONE HYDROGEL LENSES	CLARITI	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI 1-DAY	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI TORIC	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	SAUFLON SELECT	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI MULTIFOCAL	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI 1 DAY TORIC	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI 1 DAY MULTIFOCAL	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI XR TORIC	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	SIMPLICITI	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	SIMPLICITI DAILY	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI ELITE	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI 1 DAY WITH TINT	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	SELECT 1 DAY	SOFT CONTACT LENS
SILICONE HYDROGEL LENSES	CLARITI 1 DAY MYOPIA MULTIFOCAL	SOFT CONTACT LENS

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