

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-859-200-1812

The Directorate of Device Testing and Clinical Engineering (EMKI)

certifies that the manufacturer:

Oculus Technologies of México S.A. de C.V.
Industria Vidriera N° 81, Industrial Zapopan Norte
45130 Zapopan, Jalisco
Mexico

with authorized representative in EU:

Sonoma Pharmaceuticals Netherlands B.V.
Boven de Wolfskuil 3, C30-C32
6049 LX, Herten/Roermond, The Netherlands

for the products / product category:

Solutions, gels and hydrogels antiseptic and high level disinfectants of super oxidation

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report: **42-382-2013**

This certificate is valid until **2023-12-11** supposed that the results of the regular yearly surveillance audits are satisfactory.

Issued by EMKI as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Issue: 2

First issued: 2018-12-12

Budapest, 2020-04-09



Head of EMKI



EMKI 2371

The authenticity and validity of the certificate are verifiable at EMKI.

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

ATTACHMENT TO EC CERTIFICATE

Page 1 of 2

Additional information for Certificate No. 5-859-200-1812

The certificate is valid for the following manufacturing sites / facilities:

Oculus Technologies of México S.A. de C.V.
 Industria Vidriera No. 81, Industrial Zapopan Norte
 Industria Maderera No. 815, Industrial Zapopan Norte
 Industria Maderera No. 106, Industrial Zapopan Norte
 45130 Zapopan, Jalisco (Mexico)

The certificate is valid for the following Class IIb products:

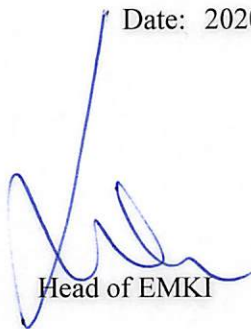
Solutions, gels and hydrogels antiseptic and high level disinfectants of super oxidation

AdvaCyn™ Wound Care	Lasercyn™
AdvaCyn™ Hydrogel	Lasercyn™ Hydrogel
Dermacyn Wound Care Solution	Microcyn Skin & Wound Hydrogel
Electromicyn ₆₀ ®	Microdacyn ₆₀ ® Wound Care
Endocyn™	Microdacyn ₆₀ ® Hydrogel
Epicyn®	Microdacyn ₆₀ ® Combo-Pack
GeloTonsil®	Microdacyn ₆₀ ® Oral Care
GramuDerm® Solution	Microdacyn ₆₀ ® Eye Care
GramuDerm® Hydrogel	Microdox ₆₀ ®
GramuDerm™ Combo-Pack	Microsafe®

Issue: 2

Date: 2020-04-09

First issued: 2018-12-12


 Head of EMKI



EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
 Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

ATTACHMENT TO EC CERTIFICATE

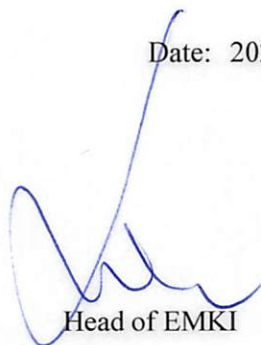
Page 2 of 2

MicrosafeCare™ Solution	MucoClyns™
MicrosafeCare™ Hydrogel	Mucocyn™
MicroSafe® Baby Cool Hydrogel	Nasocyn™
MicroSafe® Face Cool Hydrogel	Ocudox™
MicroSafe® Foot Cool Hydrogel	Pediacyn®
MicroSafe® Lady Cool Hydrogel	Pediacyn™ Dermal Spray
MicroSafe® Lady Cool Solution	Periocyn™
Microsafe Eyelid Treatment	Sebuderm Topical Gel
Microsafe Nasal Cleansing Spray	Sinudox™
Microsafe Oral Care	

Issue: 2

Date: 2020-04-09

First issued: 2018-12-12



Head of EMKI



EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)