

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.

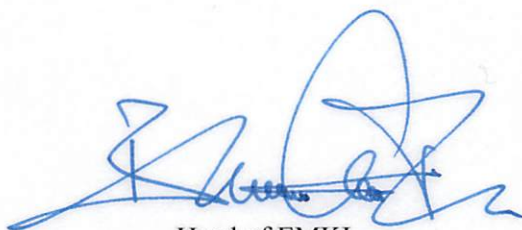
Registry number of the related audit report: **42-382-2013**

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.

Budapest, 2018-12-12



Head of EMKI



EMKI 2139

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

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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:

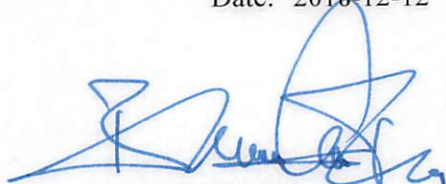
Solutions, gels and hydrogels antiseptic and high level disinfectants of super oxidation

AdvaCyn™ Wound Care	Microsafe®
AdvaCyn™ Hydrogel	MicrosafeCare™ Solution
Electromicyn60®	MicrosafeCare™ Hydrogel
Endocyn™	MicroSafe® Baby Cool Hydrogel
Epicyn®	MicroSafe® Face Cool Hydrogel
GeloTonsil®	MicroSafe® Foot Cool Hydrogel
GramaDerm® Solution	MicroSafe® Lady Cool Hydrogel
GramaDerm® Hydrogel	MicroSafe® Lady Cool Solution
GramaDerm™ Combo-Pack	MucoClyns™
Lasercyn™	Mucocyn™
Lasercyn™ Hydrogel	Nasocyn™
Microdacyn60® Wound Care	Ocudox™
Microdacyn60® Hydrogel	Pediacyn®
Microdacyn60® Combo-Pack	Pediacyn™ Dermal Spray
Microdacyn60® Oral Care	Periocyn™
Microdox60®	Sinudox™

Issue: 1

Date: 2018-12-12

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Head of EMKI



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