EC CERTIFICATE

Number: 3901526CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Sanoculis Ltd.
10 Landau St.
Kiryat-Ono 5555110
Israel

For the product category(ies)

Ophthalmic surgical devices for use in glaucoma for anterior chamber penetration for reduction of elevated intraocular pressure

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 3901510CN, initially dated 24 October 2016
Addendum, initially dated 17 March 2017

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 March 2024
Issued for the first time: 17 March 2017
Revised: 20 October 2020
Reissued: 6 March 2019
DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 3901526CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Ophthalmic surgical devices for use in glaucoma for anterior chamber penetration for reduction of elevated intraocular pressure

Issued to:

Sanoculis Ltd.
10 Landau St.
Kiryat-Ono 5555110
Israel

This certificate covers the following product(s):

- Minimally Invasive Micro Sclerostomy (MIMS) system with MIMS® Activation Device and MIMS® Surgical Device Disposable Handpiece (DHP)
- Minimally Invasive Micro Sclerostomy (MIMS) system with MIMS® Activation Device and MIMS®1A Surgical Device with multi-use Handpiece

Initial date: 17 March 2017

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

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Certification Manager

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