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

DECLARATION OF CONFORMITY

medical devices

We hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by the "CE Marking of Conformity Certificate", reference number : 3901526CE01, issued on March 17th, 2017 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

This Declaration of Conformity is valid throughout the validity period of the above mentioned CE Certificate of Conformity.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIa under Rule 6 and 9, Annex IX of the Medical Device Directive 93/42/EEC meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA certification B.V.

This declaration is supported by the Quality System certification based on ISO 13485:2016 and the harmonized standard EN ISO 13485:2016, Quality System Certificate with reference number: : 3901510, issued on (October 25th, 2016) and delivered by DEKRA Certification B.V.

This Declaration of Conformity covers Ophthalmic surgical devices as specified in the product - list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site(s):

Name and address of Manufacturer:	Sanoculis Ltd., 10 Landau, Kiryat Ono, Israel, 5555110,
European Authorized Representative:	MedNet EC-REP GmbH Borkstrasse 10 48163 Münster, Germany

Place of Issue: Kiryat Ono, Israel.

Date of issue: 28 October, 2020

Authorized by: _____

Nir Israeli, CEO

Annex: Product list

Annex to the Declaration of Conformity (Product list)

Sanoculis Ltd.,
10 Landau, Kiryat Ono,
Israel, 5555110,

PRODUCT LIST

Ophthalmic surgical devices

This product list belongs to the Declaration of Conformity (above) and specifies the CE marked products concerned that Sanoculis Ltd intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. The following list identifies the products by name and number

Product name	Product Number	Time related information
MIMS® Device	MMS1000	• P/N DHP-01000: MIMS® Surgical Device **End-of-life, no devices were placed on the market** • P/N A32-000: MIMS® Surgical Device First Batch No. **N.A** • P/N A30-000: MIMS®1A Surgical Device First Batch No. **N.A** • P/N AS1000: MIMS® Activation Device First Serial No. **2017-03-001** • P/N AS1001: MIMS® Activation Device Type ASx1 First Serial No. **N.A**

Place of Issue: Kiryat Ono, Israel

Date of issue: 28 October, 2020

Authorized by: _____
Nir Sanoculis, CEO