

CE_{2409}

CE DECLARATION OF CONFORMITY

According to Annex II of the Council Directive 93/42/EEC concerning medical devices

We: Panaxia Ltd., 1 Bat Sheva St., Lod, 7116002, Israel (Phone: +972-722744144; FAX: +972-722744145)

Declare under our sole responsibility that the products distributed under Brand Name

Crystalys Lidocaine

Meet the provisions of the Council Directive 93/42/EEC concerning Medical Devices, which apply to it: The products intended to be use as an injectable implant for soft tissue augmentation.

Therefore are in Class III, according to rule #13 of Annex IX of the Medical Device Directive. Conformity assessment performed according to Annex II.

The products fulfill the essential requirements of Annex I of the Medical Device Directive.

Conformity assessment performed by:

CE Certiso Ltd.

NB 2409

H-2040 Budaors, Gyar u. 2. Hungary.

Phone +36 23 880 830; Fax +36 23 880 831

Authorized representative who has been empowered to enter into commitments on our behalf:

MedNet GmbH - Borkstrasse 10, 48163 Muenster, Germany, Phone +49 251 322660; Fax +49 251 3226622

Certificates:

EC certificate - Full Quality Assurance System: 144493-14-06-10

Valid from: 29/12/2016 First Issue 10/06/2014 Until: 09/06/2019

EC Design Examination Certificate: 144655-16-12-29

Valid from: 29/12/2016 Until: 09/06/2019

Eran Goldberg – CEO

Date